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September 13, 2021

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements (CMS-1751-P)

Dear Administrator Brooks-LaSure:

On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2021 Medicare Physician Fee Schedule proposed rule (CMS-1751-P) published in the *Federal Register* on July 23, 2021.

The ACS is a scientific and educational association of surgeons founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Since a large portion of our members' performance and reimbursement is measured and paid for under the provisions contained in this rule, the College has a vested interest in CMS' Medicare Physician Fee Schedule (PFS) and the Quality Payment Program (QPP).With our 100-year history in developing policy recommendations to optimize the delivery of surgical services, lower costs, improve program integrity, and make the U.S. healthcare system more effective and accessible, we believe that we can offer insight to the Agency's proposed modifications to the PFS and QPP. Our comments below are presented in the order in which they appear in the rule.

PROVISIONS OF THE PROPOSED RULE FOR THE PFS

Changes to Direct PE Inputs for Specific Services

Clinical Labor Pricing Update

In 2019, CMS began a four-year phase-in of an update to the supplies and equipment prices used for code-level direct practice expense (PE) calculations. CY 2022 will be the final year of this four-year transition. In addition, for CY 2022, the Agency proposes to update PE clinical labor rates. This means that for CY 2022, changes would be made to the pricing of all three components of PE RVUs: clinical labor (CL), supplies, and equipment.

CMS states that the CL rates were last updated in CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available. A review of the full discussion in the CY 2002 MPFS final rule regarding the process of updating the CL rates shows that 12 (40 percent) of the 31 total staff types used "other sources" (e.g., SalaryExpert, powered by the Economic Research Institute) for pricing. Each of the examples of other sources represent data that are not readily available for public review to determine if the same process of collection is used. The Agency states that SalaryExpert salaries are developed using mainly government sources; however, the website for SalaryExpert indicates data are gathered from three sources: surveys conducted by SalaryExpert, surveys purchased from other organizations, and reports from publicly traded organizations.[1] This adds a layer into the process that is not transparent and could introduce bias into the pricing update. We question if CMS compared the data from SalaryExpert to the BLS data.

For CY 2022, 14 (44 percent) of the 32 single staff types are being updated using a BLS crosswalk because an exact match is not available. CMS solicits comments on the proposed updated CL pricing as well as methods to identify the most accurate types of BLS categories that could be used as proxies to update pricing for CL types that lack direct BLS wage data. The Agency is also interested in additional wage data that may be available. We provide comments in the table below on the proposed pricing source/crosswalk for select CL codes.

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[1] SalaryExpert. (2021). *About us: Our process.* Retrieved from https://www.salaryexpert.com/aboutus

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ACS Comments on Proposed BLS Crosswalk for Clinical Labor Pricing Update				
Clinical Labor Code	**Current Labor Description**	**2022 NPRM Update Source/ Crosswalk (Proposed)**	**BLS Update Source Description**	**ACS Comments**
L037B	Histotechnologist*	BLS 29-9098	Health Information Technologists, Medical Registrars, Surgical Assistants, and Healthcare Practitioners and Technical Workers, All Other	**Disagree**: We disagree that BLS 29-9098 is a correct crosswalk for CL code L037B. **We believe that BLS 29-2010 (Clinical Laboratory Technologists and Technicians) more accurately describes the clinical staff type associated with CL code L037B.**
L037C	Orthoptist*	BLS 29-1141	Registered Nurses	**Disagree**: 1. CL code L037C is incorrectly assigned to the Current Procedural Terminology (CPT) code 62304. **The correct staff code for CPT code 62304 is L037D (RN/LPN/MTA), not L037C.** 2. CL code L037C is assigned to two other CPT codes (67343 and 67346). For these CPT codes, the "orthoptist" is a new staff type that was introduced to differentiate an orthoptist from CL code L038A (COM/COT/RN/CST) as a lower-level clinical staff. Therefore, it is not correct to crosswalk this staff type to BLS 29-1141, since it would elevate the staff type above L038A. **We believe that BLS 29-2057 (Ophthalmic Medical Technician) more accurately describes the clinical staff type associated with CL code L037C.**

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ACS Comments on Proposed BLS Crosswalk for Clinical Labor Pricing Update				
Clinical Labor Code	**Current Labor Description**	**2022 NPRM Update Source/ Crosswalk (Proposed)**	**BLS Update Source Description**	**ACS Comments**
L037E	Child Life Specialist*	BLS 21-1023	Mental Health and Substance Abuse Social Workers	**Disagree**: CL code L037E is related only to one CPT code (99170: *Anogenital exam of trauma to a child*). The description of work provided to the American Medical Association (AMA)/ Specialty Society RVS Update Committee (RUC) for this clinical staff was "primarily to provide distraction to patient during the physician's exam." A child life specialist was described as a professional armed with a strong background in child development and family systems who promotes effective coping through play, preparation, education, and self-expression activities—not child mental health or substance abuse treatment. **We believe that BLS 21-1021 (Child, Family, and School Social Workers) more accurately describes the clinical staff type associated with CL code L037E.**
L038B	Cardiovascular Technician*	BLS 31-2011	Occupational Therapy Assistants	**Disagree**: BLS 29-2031 (Cardiovascular Technologists and Technicians) is a **direct crosswalk** for CL code L038B.
L039A	Certified Retinal Angiographer*	BLS 29-2010	Clinical Laboratory Technologists and Technicians	**Disagree:** CL code L039A is not related to clinical labs—instead, this staff sets up the IV for a patient, injects dye, and takes images of the eyes. **We believe that BLS 29-9000 (Other Healthcare Practitioners and Technical Occupations) or BLS 29-2057 (Ophthalmic Medical Technician) more accurately describes the**

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				clinical staff type associated with CL code L039A.
L039C	Psychometrist*	BLS 21-1029	Social Workers, All Other	**Disagree:** CL code L039C is only related to one CPT code (96138) for one minute of time for a technician to score a paper psychiatric test by hand. **We believe that BLS 31-1133 (Psychiatric Aide) more accurately describes the clinical staff type associated with CL code L039C.**
L041A	Angio Technician*	BLS 29-9000	Other Healthcare Practitioners and Technical Occupations	**Disagree:** CL code L041A was previously crosswalked to BLS 29-2034 (Radiologic Technologists and Technicians). **We believe that BLS 29-2034 remains the correct crosswalk for an angiography technician.**
L043A	Mammography Technologist*	BLS 29-1126	Respiratory Therapists	**Disagree:** Mammography technologists do not perform the same work as respiratory therapists. **We believe that BLS 29-2034 (Radiologic Technologists and Technicians) more accurately describes the clinical staff type associated with CL code L043A.**
L045A	Cytotechnologist*	BLS 29-2035	Magnetic Resonance Imaging Technologists	**Disagree:** The work performed by a cytotechnologist in a lab is not the same as that provided by an MRI technologist with a patient. CL code L045A was previously crosswalked in 2002 to BLS 29-2010 (Clinical Laboratory Technologists and Technicians) without objection by pathologists.

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Clinical Labor Code	**Current Labor Description**	**2022 NPRM Update Source/ Crosswalk (Proposed)**	**BLS Update Source Description**	**ACS Comments**
				We believe BLS 29-2010 remains the correct crosswalk for CL code L045A.
L045B	Electron Microscopy Technologist*	BLS 29-1124	Radiation Therapists	**Disagree:** For CY 2002, pathologists recommended that the labor rate for an electron microscopy technologist should be crosswalked to a cytologist. **Therefore, BLS 29-2010 Clinical Laboratory Technologists and Technicians is the correct crosswalk for CL code L045B** (i.e., CL codes L045A and L045B should have the same crosswalk and the same labor rate).
L063A	Medical Dosimetrist*	BLS 19-1040	Medical Scientists	**Disagree:** BLS 29-2098 (Medical Dosimetrists, Medical Records Specialists, and Health Technologists and Technicians, All Other) is a **direct crosswalk** for CL code L063A.
L152A	Medical Physicist	BLS 19-2012 (75th percentile)	Physicists	**Disagree:** The rationale to use the 75th percentile is based on maintaining the historical wage level for CL code L152A, which defeats the purpose of updating CL rates. In addition, the prior labor rate was set using a society salary survey from 1999. There are several types of physicists listed in the BLS files—**BLS 19-2012 (Physicist)** is the highest of the three options and would suffice as a crosswalk without using the 75th percentile rate. Alternatively, **BLS 19-1040 (Medical Scientist)** would also be an appropriate crosswalk without more specific data.

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Clinical Labor Code	**Current Labor Description**	**2022 NPRM Update Source/ Crosswalk (Proposed)**	**BLS Update Source Description**	**ACS Comments**
L038A	COMT/COT/RN/ CST	BLS 29-2057	Ophthalmic Medical Technicians	**Disagree**: We disagree with crosswalking a certified surgical technician (CST) to BLS 19-4010. **BLS 29-2055 (Surgical Technologist) is a direct crosswalk for CL code L038A.**
		BLS 29-2061	Licensed Practical and Licensed Vocational Nurses	
		BLS 29-1141	Registered Nurses	
		BLS 19-4010	Agricultural and Food Science Technicians	

We highlight additional concerns with several proposed factors for the CL pricing update calculation below.

- Mean versus median BLS wage data: CMS proposes to use the average (mean) hourly wage instead of the median. We disagree that the mean is the correct data to use for the following reasons:

    1) The clinical staff time for codes is always based on the "typical" or median time when survey data are used. The most recent example of this is the clinical staff times assigned to activities for the office or other outpatient evaluation and management (E/M) visit code set updated for CY 2021; median survey times were recommended by the RUC and approved by CMS.

    2) The BLS survey data include rates for many "industries" including hospitals, physician offices, nursing care facilities, and government services. The data for registered nurses show that government and hospital pay rates are significantly higher than physician office pay rates. This discrepancy is similar for other clinical staff types. By proposing the mean salary instead of the median salary, equal weight is placed on the higher salaries in facility and government settings, even though the majority of CL changes will impact pricing for non-facility (office) settings. We do not suggest that any specific "industry" category be used for pricing but wish to highlight that the median rate will reflect the typical rate, and no additional code-level work would be required because the BLS

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tables all list the median statistic. We recommend that CMS use the BLS median wage rate to update CL pricing.

- Fringe benefit multiplier: To account for employers' cost of providing fringe benefits, such as sick leave, CMS proposes to use the same benefits multiplier of 1.366 that was utilized in CY 2002. We disagree with this proposal as this multiplier is not accurate according to current BLS data. The most recent news release bulletin for "Employer Costs for Employee Compensation" from the U.S. Department of Labor indicates that the private industry worker's median and mean benefit cost was 29.6 percent.[2] We believe that the private industry workers rate is appropriate as it eliminates overemphasis on non-healthcare wages, such as those for farmers and federal employees. **We recommend that CMS use the current fringe benefit multiplier of 1.296 in the calculation to update CL rates.**

- Pricing update implementation: CMS notes that the potential effects of the CL pricing update on specialty payment impacts are largely driven by the share of labor costs associated with the direct PE inputs for each specialty. The specialties disproportionately impacted by this proposed update typically perform office-based services that utilize expensive supplies and equipment. The ACS, AMA, and numerous other medical societies have advocated annually for CMS to resolve the problem related to high-cost supplies by establishing Healthcare Common Procedure Coding System (HCPCS) Level II codes for supplies that exceed $500. During the COVID-19 public health emergency (PHE), the ability to provide limb-saving interventions in an office kept many patients out of the hospital setting and away from COVID-19 patients. By not fixing the issue of high-priced supplies embedded in the PE for procedures in the office, the resulting direct PE payment for these services will now be 44 percent of the actual PE cost to provide the service. This cost inhibitive update will likely limit providers' ability to perform these services in the office, as the cost of providing such services will be higher than the office's income stream can justify. Providers will thereby be forced to send their patients to facilities where patient-care resources are already strained due to the PHE. **We strongly urge CMS to address this problem now by establishing HCPCS Level II codes for all supply items that exceed $500.**

  In addition, we note that there are several specialties that will be disproportionately impacted by both the CL rate update (due to the

[2] Bureau of Labor Statistics. (2021). *News release: Employer costs for employee compensation—March 2021* (USDL-21-1094). U.S. Department of Labor. Retrieved from https://www.bls.gov/news.release/pdf/ecec.pdf

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embedded high-priced supply items) and the final transition year of repricing supplies and equipment. For example, the estimate for vascular surgeons is a 4 percent decrease due to changes in clinical labor and a 4 percent decrease due to changes in supply and equipment pricing. On top of these decreases is the scheduled expiration of the one-year 3.75 percent increase to the conversion factor provided by the Consolidated Appropriations Act for CY 2021. Therefore, the true impact on vascular surgeons is estimated to be a decrease of almost 12 percent. This percentage, however, is significantly greater (-20 percent) for those providers that perform limb-saving procedures that include high-cost supplies and equipment. We believe that a 20 percent decrease in reimbursement in one year will render many practices financially defunct, which will ultimately impact patients' access to timely care.

CMS also indicates that when updates to a payment methodology based on new data produce significant shifts in physician reimbursement, the Agency considers whether it would be appropriate to implement the updates through a phased transition across several calendar years. **We agree that it would be most equitable for the proposed CL pricing update to be phased-in over four years, and we request that the Agency delay implementation of the CL pricing update until CY 2023 after the final transition year of the supply and equipment pricing update.** If CMS were to delay implementation of the CL rate update for one year, stakeholders will have more time to respond to the Agency's request for additional information about other wage price data that may be more appropriate than the proposed BLS crosswalks. The sixty-day comment period allotted for the CY 2022 MPFS is not enough time to respond to a proposed update that decreases the direct PE scaling factor in the PE calculation by -25 percent, from 0.5916 to 0.4468.

To address the concerns described above, we strongly urge CMS to take the following actions:

- Consider recommendations for alternate BLS crosswalk labor categories for selected CMS PE labor staff types;
- Use the BLS median wage rate for updated pricing;
- Apply a fringe benefit multiplier of 1.296 in the calculation to update clinical labor rates;
- Establish HCPCS Level II codes for all supply items that exceed $500;
- Phase-in the clinical labor rate update over four years; and
- Delay implementation of the CL pricing update until CY 2023 after the final transition year of the update to supply and equipment items.

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Comment Solicitation for Codes Involving Innovative Technology

As part of its proposal to establish values for remote retinal imaging, CMS requests broad comments on the resource costs for services involving the use of innovative technologies including, but not limited to, software algorithms and artificial intelligence (AI). **We provide feedback on the questions CMS presented in the rule, but we also urge CMS to examine the overall impact of new technologies on quality, cost, workflow, team-based care, physician burden, communication, and more.** These are interrelated issues, so it is not possible to examine the impact of new technologies in these areas in silos.

1. **To what extent are services involving innovative technologies such as software algorithms and/or AI substitutes and/or supplements for physician work? To what extent do these services involving innovative technology inform, augment, or replace physician work?**

Advances in technology, software algorithms, and AI are seen across multiple sectors of the U.S. economy. These technologies can further productivity and enrich knowledge and applied science, but can also create new work needed to leverage the outputs from the technology. These technologies also impact workflows depending on the purpose of the technological advancement.

These principles of technology changing the work that humans do also apply to the use of innovative technology in healthcare. For example, advances in surgical instrumentation have led to our ability to reach more patients with more complex therapies. Technology has also led to greater customization of care and better management of various cohorts. But with these changes come changes to the work of physicians. When considering how such digital tools would change physician work, it is important to think beyond the current state of applied science and consider the applications of expanded technological capabilities and knowledge.

While use of innovative technologies should never substitute or supplant physician work, they can serve a vital role in aiding clinicians' function and can augment—and in some instances change —the nature of physician work. Examples include technologies and AI that read and process imaging or the IDx-DR device that can assist in detecting diabetic retinopathy.[3] Surgical examples include the Predictive Optimal Trees in Emergency Surgery Risk (POTTER) risk assessment calculator app that uses AI to predict an emergency general surgery patient's risk of death, and the MySurgeryRisk

[3] Digital Diagnostics (2021). IDx-DR. Retrieved from https://www.digitaldiagnostics.com/products/eye-disease/idx-dr/.

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machine learning (ML) algorithm that predicts risk scores for major postoperative complications.[4,5]

These technologies can enhance, add to, or otherwise change the work that physicians do, but such tools will continue to require human oversight. In addition, physicians should always have the final say about if and to what extent to rely on digital tools. Differences in physician training, standards of care, care environments, patient goals, and more will have an impact on how clinicians view recommendations and outputs from digital health tools using innovative technologies. What works for one system or clinician may not work for another.

2. **How has innovative technology such as software algorithms and/or AI affected physician work time and intensity of furnishing services involving the use of such technology to Medicare beneficiaries?**

New technologies do not categorically increase or decrease physician work time and intensity; rather new technologies change what physicians do. There are many benefits to using digital health technologies in healthcare practices such as improved efficiencies, improved access, reduced healthcare costs, increased quality, and more personalized care for patients. These tools and technologies can also give healthcare providers a holistic view of their patients' health through data collected from of wearables and personal health applications, as well as increased ability to readily communicate and exchange information with other providers. But care can become increasingly complex with additional data, recommendations, access to clinical practice guidelines, and more at the physicians' fingertips. With this more complete view of the patient comes a different type of work for the physician, and the amount of information being aggregated across time in a care plan could even be overwhelming. In some instances, using innovative technology might reduce work time, but it can also increase time and/or intensity due to the increased data to review and knowledge necessary to interpret the outputs and recommendations.

It is also important to consider that in the last decade, healthcare has focused on care coordination. Part of the reason for this is that care plans now involve care teams, each contributing services while patients travel across the care

[4] Maurer, L., Chetlur, P., Zhuo, D. et al. (2020). Validation of the AI-based Predictive OpTimal Trees in Emergency Surgery Risk (POTTER) calculator in patients 65 years and older. *Annals of Surgery.* https://pubmed.ncbi.nlm.nih.gov/33378309/

[5] Bihorac, A., Ozrazgat-Baslanti, T., Ebadi, A., et al. (2019). MySurgeryRisk: Development and validation of a machine-learning risk algorithm for major complications and death after surgery. *Annals of Surgery, 269*(4), 652-662. https://pubmed.ncbi.nlm.nih.gov/29489489/

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continuum. New technologies and tools using AI and ML can play a role in allowing clinicians to expand their ability to coordinate care. These expansions represent opportunities to extend the care teams even further. So, it is not possible to think in terms of the way that care has been delivered in the past and how new technologies could affect the physician work time and intensity of specific CPT codes. Tools using AI and ML are not merely additions to a static delivery of care; rather, they represent a new set of instruments that will be used by the evolving care teams to better provide for patients.

3. **How is innovative technology such as software algorithms and/or AI changing cost structures in the physician office setting? Do costs for innovative technology such as software algorithms and/or AI to furnish services to patients involve a one-time investment and/or recurring costs? How should CMS consider costs for software algorithms and/or AI that use patient data that were previously collected as part of another service? As technology adoption grows, do these costs decrease over time?**

It is early in the adoption of tools using AI and ML in healthcare. Many of the costs related to these technologies are largely unknown. For now, we recognize that knowledge sharing enabled by AI and ML is tied to technology such as electronic health records (EHRs) and participation in health information exchanges (HIEs) or other state or federal data systems. In addition to the capital costs and maintenance of these aspects of technology, the licensing and maintenance of the intellectual property associated with AI and ML are unknown. Simply maintaining Fast Healthcare Interoperability Resources (FHIR) servers that allow for open standards-based data exchanges have proven costly. ACS members also frequently share that opening their EHR systems to AI and ML dramatically increases their costs with software vendors. Accessing openly available AI and ML may be so cost prohibitive due to EHR vendor demands that these could almost appear to be monopolistic. The results would create excessive recurring costs.

As the nation quickly rolled out EHRs, we never envisioned the environment for open-source software, FHIR, and other aspects of shared knowledge using digital services. The field of shared medical knowledge and knowledge management with AI and ML are nascent in healthcare and require that we retrofit these enhancements to care in a hardened environment of EHR vendors. Solutions from Amazon, Microsoft, and others are aiding in creating the necessary workarounds for a knowledge environment that relies on healthcare data lakes that exist outside the EHR walls. These are exciting enablers of sharing knowledge. However, it is difficult to say what the capital

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start-up needs are and what the recurring costs will be. There are still too many unknowns.

Turning more directly to the individual physician, we are still learning how the use of innovative technologies can change cost structures in the physician office setting. What we do know is that innovative technologies can change the overall workflow of a physician office, which can impact the cost structure in multiple ways. **Use of innovative technology is not just an added cost in exchange for making a current process more efficient. Rather, new technologies can change a physician's entire workflow, how physicians and patients communicate, and the data that clinicians and patients can access.** Digital heath tools and technologies can enable complex data modeling, use of statistics and predictive analytics, access to the most current clinical practice guidelines and clinical decision support software, and ultimately knowledge sharing and knowledge management. The ultimate goal is to improve quality and value through providing the most relevant health care information to the right people, at the right time, in the right ways to enable them to make the most well-informed and cost-effective patient care decisions. As a result, reduced costs can come from improved patient care, decreased readmissions, reducing redundancy in knowledge, access to clinical pathways and guidelines, and more.

We also know that some of our members are experiencing much higher costs as they use innovative technologies. We have heard anecdotally that implementing the MySurgeryRisk risk score for postoperative complications can cost over $100,000 for an IT team to map and validate. Then the tool must be reviewed every few months to ensure that recommendations of the AI algorithm are correct and that relevant factors for the use of this tool have not changed, which is not a one-time investment. Use of innovative technology has great potential to improve patient care, but it can come with high institutional and maintenance costs. Also, there is no guarantee that physicians or institutions will recoup their investment in new technology. Or worse yet, in some instances, investments in the new technology could be lost altogether if the technology itself does not function properly like the highly touted Epic Sepsis Model, which only poorly predicted sepsis.[6] Finally, the costs of using innovative technologies might not be affordable for smaller practices, so the impact of these new digital health tools will be uneven for some time.

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[6] Wong, A., Otles, E., Donnelly, J., et al. (2021). External validation of a widely implemented proprietary sepsis prediction model in hospitalized patients. *JAMA Internal Medicine, 181*(8), 1065-1070. https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2781307

4. **How is innovative technology affecting beneficiary access to Medicare-covered services? How are services involving software algorithms and/or AI being furnished to Medicare beneficiaries and what is important for CMS to understand as it considers how to accurately pay for services involving software algorithms and/or AI?**

The questions posed are focused on the traditional face-to-face transactions of Medicare, which seems constraining to new technologies using AI and ML. In addition, beneficiaries are starting to seek more knowledge about their health and healthcare. **Technology can both improve access and create barriers to access**. On the one hand, we view digital services with AI and ML as able to provide three categories of knowledge enhancement that can also improve access:

1) Clinical decision support (CDS), which can provide patients with a better understanding of their care journey and expectations for care.
2) Population management, which can be improved using shared knowledge and fewer clinical resources. Understanding various cohorts, such as diabetes, ischemic heart conditions or cancer may inform patients and clinicians about their outcomes and care delivery.
3) Technology can also enhance research, which can eventually improve access. Patients and clinicians would have awareness of research opportunities, especially when traditional care pathways have been exhausted and patients inquire about what more may be available.

In addition, if a practice's business model cannot fully support the clinical needs of the community, it is possible that a digital tool could provide enhancements to increase access. Telehealth and remote patient monitoring devices can also expand access for patients who live in rural areas, are homebound, or have transportation or other obstacles to traditional delivery of healthcare services.

However, these benefits are limited by the digital divide, which prevents many who need it from being able to use these new technologies. Patients with limited access to broadband and other digital services may be left out as our health system continues to rely more on digital health. In addition, knowledge management in the complex disciplines of healthcare requires human-human interfaces to interpret the value of the knowledge imparted and to aid patients and their families in decision making. Approaches using new technology that specifically aim to improve access would likely drive significant improvement in quality of care for those patients given that access is often the limiting factor in their interaction with the system.

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5. **Compared to other services paid under the PFS, are services that are driven by or supported by innovative technology such as software algorithms and/or AI at greater risk of overutilization or more subject to fraud, waste, and abuse? As CMS is considering appropriate payment for services enabled by new technologies, there are considerations for program integrity. To what extent do services involving innovative technology require mechanisms such as appropriate use criteria to guard against overutilization, fraud, waste, or abuse?**

Any new technology will be at risk for fraud and overutilization. Particularly with the use of AI-based tools or CDS software, these technologies could recommend tests or services that are not needed. **As mentioned previously, the need for clinician oversight of the technology is key. Use of new technology should also be monitored closely as new reimbursement strategies and business models are employed.**

An example of a tool that uses standards to make sure it is safe and informative is the NSQIP Surgical Risk Calculator, which provides a patient-customized risk assessment for major surgical procedures and is maintained and openly provided by the ACS. Using this digital application in surgical decision-making and informed consent has become increasingly more common for patients with high-risk surgical needs. This clinical tool requires that the algorithms used to establish the risk results meet standards for clinical excellence, rely on current data, and are regularly reviewed and updated. Once these standards are met, the use of the tool is safe and informative to patients and the care team. Not all risk calculators for surgical care would stand up to the scrutiny applied to the ACS standard. Criteria are needed to assess and endorse the digital tools used in care environments.

6. **Compared to other services paid under the PFS, are services driven by or supported by innovative technology such as software algorithms and/or AI associated with improvements in the quality of care or improvements in health equity? Additionally, taking into consideration that a software algorithm and/or AI may introduce bias into clinical decision making that could influence outcomes for racial and ethnic minorities and people who are socioeconomically disadvantaged, are there guardrails, such as removing the source of bias in a software algorithm and/or AI, that Medicare should require as part of considering payment amounts for services enabled by software algorithm and/or AI?**

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This question asks about the effect of technology on healthcare quality, health equity, and bias. These are three separate and distinct issues that can often be intertwined.

Quality

There are many years' worth of data to suggest that technology has improved quality of care for patients. Healthcare is a knowledge-driven industry and delivery of quality services is heavily dependent on the ability of clinicians to access timely, relevant data and information. **One of the most important goals in improvements in technology is that it has the potential to drive optimal outcomes in the effectiveness, efficiency, and safety of patient care, all resulting in improvements in quality.** For example, technology can be used to assist institutions that are not providing guideline concordant care because they are in a rural setting, may be underfunded, or for other reasons. A tool that enables such institutions to access not only static guidelines, but continuous living assessments of knowledge could play a significant role in improving quality. The guidelines could be adjusted for various factors, such as demographics, social determinants of health (SDOH), completeness of therapy, compliance to therapy, and others to better guide physicians as they care for patients. But, as we described above, the improvements in quality could be limited to those who have access to technology, so it is also important to be aware of how technology could play a role in further widening the disparity gap.

Equity and SDOH

Although often conflated, addressing equity and SDOH are not the same. But, as discussed in other sections of this letter, there is a clear connection between SDOH factors and surgical outcomes. **Efforts to provide surgeons with accurate and real-time SDOH data could improve care delivery of healthcare and could in turn improve healthcare equity.**

We envision many instances where these data can be used to provide more personalized healthcare services for patients. For example, when a patient is admitted for a surgical procedure, having up-to-date information about the patient's chronic care management plans and patient-generated data that show their average activity levels, heart rate, insulin tracking, and other health information could greatly impact the way a surgeon decides how they educate and prepare the patients in the preoperative phase of care. The surgeon might also have access to self-reported information about social risk factors from patient surveys that could assist them in developing more personalized postoperative recovery and follow-up plans to ensure optimal recovery.

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If the collection of these data were more commonplace, we envision integrating it into clinical workflows through CDS modules available through the physicians' EHR and other platforms. The CDS tools could apply algorithms that evaluate the patient's electronic health information (EHI), including other risk variables, to trigger follow-up reminders and alerts for certain medications or interventions specific to the patient's needs.

To achieve more widespread collection, aggregation, and tracking of SDOH data, improvements in collection methodologies and standardization are necessary across the entire healthcare system. In many instances these data are not widely collected, and if they are, there is variation in how it is identified, classified, and what fields are used in EHRs and other systems. While some systems have taken steps to develop and implement internal processes to administer surveys and gather self-reported data from patients, these practices are not widely adopted and there is still much to be done to address the gaps.

Bias

It is critical to consider bias when designing, training, and using digital health tools. Various forms of bias based on race, ethnicity, gender, sexual orientation, socioeconomic status, and more can be perpetuated through using certain advanced digital health tools, especially those using AI/ML. Bias can manifest in digital tools in various ways. For instance, if an AI algorithm were trained with data that fails to include all patient populations for which the tool is used, this would introduce inherent bias. Bias could also be unintentionally written into algorithms, leading to outputs that could have a biased impact on certain populations. The context in which the tool is used should also be considered when trying to avoid bias. If the tool were trained on a certain population for a specific purpose and is instead applied in a different setting, with a different patient population, with varying risk factors, this could result in bias.

While it is not possible to eliminate bias completely, steps can be taken to validate the quality of the data and reduce bias in AI/ML algorithms. **Building a framework, through collaboration with stakeholders with clinical and technical expertise, that guides the development and validation of algorithms can assist in reducing bias if done with a high level of rigor.** The framework could include a checklist with certain steps that developers would have to complete to ensure algorithms have gone through rigorous testing and validation. By following the processes and validation criteria set forth by the framework, developers can work to reduce bias and improve the accuracy of output predictions. This type of framework, coupled with external

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validation that utilizes data across various practice settings and demographics, can also be applied periodically following the implementation of the tool to ensure as the algorithms take in real-time data, they are still achieving a high-level of accuracy.

In addition to building a framework to validate these algorithms, efforts to expand the data infrastructure to capture validated clinical data as well as racial, ethnic, and SDOH variables, will support the development of accurate predictive algorithms. Instead of building databases in silos where some focus on capturing clinical and outcomes data and others capture public health and disparities variables, creating a master database that can integrate all these elements will be beneficial in developing digital tools and using data to better understand variation in outcomes across populations. These databases could integrate data from trusted sources such as patient surveys collected during visits and secure apps on personal devices. Using more expansive data sets will help reduce the gaps in data that are used to develop predictive models, therefore allowing the models to "learn" how to aggregate greater variations in data elements.

Telehealth and Other Services Involving Communications Technology

Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis

CMS proposes to allow certain services added to the Medicare telehealth list to remain on the list to the end of December 31, 2023, so that there is a glide path to evaluate whether the services should be permanently added to the telehealth list following the COVID-19 PHE. **We thank CMS for its continued efforts to expand access to care via telehealth during the pandemic and encourage the Agency to thoroughly review all services temporarily added to the Medicare telehealth list to ensure such services remain safe and appropriate to furnish virtually post-PHE before they are made permanently eligible for telehealth coverage.**

Implementation of Provisions of the Consolidated Appropriations Act, 2021 (CAA)

The CAA of 2021 included a number of provisions pertaining to Medicare telehealth services furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder that CMS proposes to enact for CY 2022. While these proposals are applicable only to mental health-related telehealth services, we believe that such provisions could eventually be more broadly applied to telehealth services at large, and we urge CMS to consider the

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following issues when establishing discrete and concise telehealth coding, billing, and documentation criteria.

- Originating sites: Medicare telehealth statute generally limits the scope of telehealth services to those furnished in rural areas and in certain enumerated types of "originating sites" including physician offices, hospitals, and other medical care settings. The CAA amended this statute to include the patient's home as a permissible originating site for telehealth services furnished to treat mental health disorders. **The ACS believes that a patient's home should be a permissible originating site for all telehealth services to reduce care barriers related to mobility and transportation, among others. However, we question if this specific statutory language referencing the "home" of the patient will inadvertently restrict beneficiaries' ability to receive telehealth services at other locations they frequent, such as their place of work.** We seek clarity from CMS regarding its interpretation of the applicable CAA amendment text.

- Conditions of payment: The CAA prohibits payment for telehealth services unless the physician or practitioner furnished an item or service to the patient in person, without the use of telehealth, within 6 months before the first telehealth service. Thereafter, the Secretary has the discretion to specify the times or intervals at which an in-person, non-telehealth service is required as a condition of payment for these telehealth services. CMS proposes that, as a condition of payment for a mental health telehealth service, the billing physician or practitioner must have furnished an in-person, non-telehealth service to the beneficiary within the 6-month period before the date of the telehealth service. The Agency seeks comment on whether a different interval, whether shorter, such as 3-4 months or longer, such as 12 months, may be appropriate to address program integrity and patient safety concerns. **We recognize that the proposed 6-month interval aligns with that specified by statute, but we believe generally that it is an arbitrary time threshold set simply to require an established patient relationship before a telehealth service is eligible for reimbursement. The Agency should base the decision of an appropriate interval on applicable medical guidelines and typical patient needs.**

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Proposed Valuation of Specific Codes for CY 2022

Closed Treatment of Nasal Bone Fracture (CPT codes 21315 and 21320)

For both CPT codes 21315 (*Closed treatment of nasal bone fracture; without stabilization*) and 21320 (*Closed treatment of nasal bone fracture; with stabilization*), CMS agrees with the RUC recommendation to change the global period assignment from 10-days to 0-days to account for postoperative care that includes variable work within 10 days. **We appreciate that the Agency approved this request for a global period change for these two codes.**

- CPT code 21315 (*Closed treatment of nasal bone fracture; without stabilization*): CMS disagrees with the RUC-recommended work relative value unit (RVU) of 2.00 for CPT code 21315 and instead proposes a work RVU of 0.96 based on the reverse building block methodology (BBM) that removes the RVUs and time associated with the 10-day global period, as shown in the table below.

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
21315	Closed treatment of nasal bone fracture with manipulation; without stabilization	1.83	2.00	0.96

CMS does not discuss or acknowledge the additional information provided by the RUC about how these codes were originally valued, and we do not believe that the Agency fully reviewed the compelling evidence testimony regarding the flawed methodology used to value this low-volume code. Specifically, details from the RUC summary of recommendation form indicate that CPT code 21315 was not reviewed during the Harvard study and indicated in the 1992 MPFS Federal Register that flagged the value for this code as "gap-filled:"

> The proposed rule provided preliminary physician work, practice expense, and malpractice RVU values for services that had been studied by the Harvard research team and explained in general terms our proposed process for "gap-filling" values not expected to be provided by Harvard.[7]

We wish to highlight that the data available in 1991 to gap-fill a value for CPT code 21315 did not include any work or time information, and instead

[7] Medicare: Physicians' Services; Fee Schedule, 56 F.R. 59624 (1991).

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relative work was assigned using magnitude estimation—considering that this is a low-volume code, it is unlikely that the gap-fill estimate was informed by actual experience in the provision of the service. The gap-filling process was followed by a second Harvard review in 1993, through which a survey of oral and maxillofacial dental surgeons was conducted to collect time for CPT code 21315, even though these providers do not perform this nasal bone fracture treatment service. These late review Harvard supplemental time data were later used in 1997 to insert an office visit (without changing work RVUs) into the time/visit data details by a CMS contractor for the purposes of implementing a new Medicare PE methodology. These three separate activities—gap-fill, Harvard late review by wrong specialty, and addition of visits by algorithm for PE purposes—produced a work RVU that was extremely low, the intrawork for CPT code 21315 was negative (-0.006).

Using reverse BBM, CMS is perpetuating the flaws of the original valuation for this service, resulting in the same negative intraoperative work value. It is clear that the Agency did not take into consideration the fact that the work RVU, times, and visit associated with CPT code 21315 were developed using multiple flawed methods. CMS' proposed work RVU of 0.96 for this code—a value almost equal to a level two E/M office/outpatient visit (CPT code 99202; work RVU=0.93)—does not accurately reflect the provision of the service. **We urge CMS to review this new information, along with RUC's discussion about a correct relative value that is based on survey data for a 0-day global code in comparison to the intensity, complexity, and time of other 0-day global codes, and to accept the RUC-recommended work RVU of 2.00 for CPT code 21315.**

- CPT code 21320 (*Closed treatment of nasal bone fracture with manipulation; with stabilization*): CMS disagrees with the RUC-recommended work RVU of 2.33 for CPT code 21320 and instead proposes a work RVU of 1.59 based on the reverse BBM to remove the RVUs and time associated with the 10-day global period, as shown in the table below.

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
21320	Closed treatment of nasal bone fracture with manipulation; with stabilization	1.88	2.33	1.59

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CMS does not discuss or acknowledge the additional information provided by the RUC about how these codes were originally valued, and we do not believe that the Agency fully reviewed the compelling evidence testimony regarding the flawed methodology used to value this low-volume code. Specifically, details from the RUC indicate that CPT code 21320 was reviewed by 17 otolaryngologists as a 90-day global code during the Harvard study. No other code in the family was reviewed and the vignette used by Harvard was "*Closed reduction nasal fracture*"—notably, the manipulation and stabilization work inherent to this service was not included in such review. The Harvard survey intraoperative time from the 17 respondents was 29 minutes. Separately, Harvard collected postoperative data that included a mean office visit time of three minutes, which was later transformed by a CMS contractor for PE methodology implementation into 0.5 x CPT code 99212. Similar to the discussion above for CPT code 21315, the initial methodology to value CPT code 21320 and the subsequent addition of an office visit to implement a PE calculation is a flawed methodology.

The Agency uses reverse BBM to subtract minute-by-minute pre-, intra-, and post-service time from the current value of CPT code 21320 even though the original valuation for this low-volume code was not developed using a minute-by-minute building block approach. Furthermore, the latest survey for this code found that total time decreased by only three minutes (-4 percent), but CMS' proposed reduction in time is -15 percent. In prior MPFS rules, CMS has acknowledged that "a minute worked is a minute worked" when referring to "work/time." The Agency has also acknowledged that non-face-to-face time spent reviewing records or placing an order for a blood test for primary care office visits is the same intensity as face-to-face time spent with a patient. In this instance, however, CMS has ignored compelling evidence and has treated time components (face-to-face versus non-face-to-face) differently for CPT code 21320, significantly reducing the RUC's recommendation by 15 percent for a service with just three minutes less total time (78 minutes versus 75 minutes).

We do not believe that CMS' proposed value for CPT code 21320 accurately reflects the provision of the service. **We urge CMS to review this new information, along with RUC's discussion about a correct relative value that is based on survey data for a 0-day global code in comparison to the intensity, complexity, and time of other 0-day global codes, and to accept the RUC-recommended work RVU of 2.33 for CPT code 21320.**

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The ACS also strongly objects to Agency's statement that the global period changes from 010-day to 0-days allow for separately billable E/M visits relating to CPT codes 21315 and 21320, which CMS uses to justify its proposed removal of RVUs it believes are attributable to the currently bundled E/M visits, totaling 1.30 RVUs for CPT code 21315 and 0.35 RVUs for CPT code 21320. **We find it egregious that CMS proposes to remove the 2021 increased work RVUs for office/outpatient E/M codes in the same rule that the Agency continues to refuse to update global code values commensurate with the CY 2021 office/outpatient E/M increases.** The nonsensical application of a reverse BBM for CPT codes 21315 and 21320 is compounded by the fact that clear evidence was provided that office visit assignment for these codes to implement a new PE methodology have no relativity to the original Harvard valuation of the codes, which was based on magnitude estimation. CMS has previously indicated that RVU proposals are developed based on internal review by the Agency's Medical Officers, and if CMS does not accept the RUC recommendations for CPT codes 21315 and 21320, **we request a peer-to-peer review** with the appropriate Medical Officers to discuss the rationale for the CMS-proposed work RVUs in addition to the compelling evidence for the work RVUs recommended by the RUC for these services.

Insertion of Interlaminar/Interspinous Device (CPT code 22867)

CMS proposes to accept the RUC-recommended work RVU of 15.00 for CPT code 22867 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level*). **We agree with CMS' decision to accept the RUC recommendation for this code.**

Treatment of Foot Infection (CPT codes 28001, 28002, and 28003)

Global Period Assignment

CPT code 28002 was identified by the RUC Relativity Assessment Workgroup through a screen of 10-day global codes with utilization greater than 1,000 and more than one postoperative visit. CPT codes 28001 (10-day global) and 28003 (90-day global) were added as family codes for review. The RUC recommended that all three codes be assigned a 0-day global period due to significant heterogeneity in the complexity of the patient population, making it difficult to identify the typical patient for the purpose of estimating typical postoperative hospital and office visits in a global period; the severity of underlying comorbidities require differing levels of follow-up care. **We**

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appreciate that CMS approved this request for a global period change for these three codes.

- CPT code 28001 (*Incision and drainage, bursa, foot*): CMS proposes to accept the RUC-recommended work RVU of 2.00 for CPT code 28001. **We agree with CMS' decision to accept the RUC recommendation for this code.**

- CPT code 28002 (*Incision and drainage below fascia, with or without tendon sheath involvement, foot; single bursal space*): CMS disagrees with the RUC-recommended work RVU of 3.50 for CPT code 28002 and instead proposes a work RVU of 2.79, as shown in the table below.

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
28002	Incision and drainage below fascia, with or without tendon sheath involvement, foot; single bursal space	5.34	3.50	2.79

The surveying specialty societies provided compelling evidence of prior flawed methodologies regarding the valuation for this code. Specifically, CMS identified CPT code 28002 as potentially misvalued in 2010 through a site-of-service anomaly screen from early 2009 claims data that showed 49.2 percent of Medicare patients receiving this service were under inpatient status. The final 2009 data indicated inpatient claims were greater than 50 percent, and the current 2019 Medicare data indicate over 60 percent inpatient status. However, because CMS erroneously flagged this code as an outpatient procedure, the RUC only allowed 0.5 x CPT code 99238 for facility work and recommended a reduction of 10 percent in the work RVU using magnitude estimation. This prior recommendation—made over 10 years ago—was based on faulty claims data and not on the RUC survey, resulting in an underestimation of work and time as CPT code 28002 was valued as an outpatient procedure despite typically and consistently being performed in the inpatient setting. In addition, prior to 2010, CPT code 28002 was misvalued based on a 1995 RUC survey by pediatricians who do not perform this service. The RUC accepted the pediatric survey data, including operative time and inpatient visits, but did not accept the pediatric-recommended work RVU because no compelling evidence was provided to increase such value.

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In developing its recommendation to CMS for CY 2022, the RUC acknowledged that both prior reviews for CPT code 28002 used flawed methodologies. The RUC considered the survey median work RVU too high and the survey 25th percentile work RVU too low in comparison to other 0-day global codes that are typically performed in an operating room on a patient with inpatient status. The RUC determined that CPT code 31287 (*Nasal/sinus endoscopy, surgical, with sphenoidotomy*; work RVU=3.50) was an appropriate crosswalk code. CMS states that because CPT code 28002 is converting from a 10-day global to a 0-day global, the Agency believes reference CPT code 43193 (*Esophagoscopy, rigid, transoral; with biopsy, single or multiple*; work RVU=2.79) is a more suitable value of 2.79 work RVUs with a similar 30 minutes of intraservice physician time and 106 minutes of total time.

We disagree with CMS' proposed crosswalk to CPT code 43193 and proposed work RVU of 2.79 for CPT code 28002. A work RVU of 2.79 is exactly equal to a calculated value based on reverse BBM and not on relativity within the MPFS. Furthermore, CMS could have chosen the next esophagoscopy code in the family as the reference—CPT code 43194 (*Esophagoscopy, rigid, transoral; with removal of foreign body(s)*) has the same 30 minutes of intraservice physician time and one minute more of total time (107 minutes) with a work RVU of 3.50—or the more recently-reviewed high-volume CPT code 58558 (*Hysteroscopy with biopsy*), which has the same 30 minutes of intraservice physician time, 106 minutes of total time, and work RVU of 4.17. We believe CMS' chosen crosswalk code was selected based on intra-time similarities after the Agency calculated a value using reverse BBM without also considering the relative intensity and complexity of work, prior misvaluation based on flawed methodologies, and compelling evidence for CPT code 28002. The RUC's review considered many 0-day global codes with 30 minutes of intraoperative time and determined that CPT code 31287, a therapeutic procedure, was a suitable clinical crosswalk. Specifically, the RUC considered all 0-day global codes with 30 minutes of intra-time and 90 to 110 minutes of total time and found 15 codes with a work RVU range of 2.47 to 6.00 and median work RVU of 4.00, placing the RUC-recommended work RVU of 3.50 for CPT code 28002 in the lower half of the code range. The diagnostic esophagoscopy code CMS chose for crosswalking purposes was second to the lowest code in this range and not consistent with the clinical work, intensity, complexity, mental effort, and judgment required for CPT code 28802.

The low work RVU of 2.79 proposed by CMS for CPT code 28802 ignores the compelling evidence regarding the prior work RVU reduction in 2010

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based on erroneous Medicare utilization claims information and survey data from the wrong specialty, both of which incorrectly devalued the code. **We urge CMS to review this new information, along with RUC's discussion about a correct relative value that is based on survey data for a 0-day global code in comparison to the intensity, complexity, and time of other 0-day global codes, and to accept the RUC-recommended work RVU of 3.50 for CPT code 28002.**

- CPT code 28003 (*Incision and drainage below fascia, with or without tendon sheath involvement, foot; multiple areas*): CMS proposes to accept the RUC-recommended work RVU of 5.38 for CPT code 28003. **We agree with CMS' decision to accept the RUC recommendation for this code.**

Per-Oral Endoscopic Myotomy (POEM) (CPT code 434XX)

In May 2020, the CPT Editorial Panel created new code 434XX to describe a peroral endoscopic myotomy procedure and was assigned a 90-day global period by CMS. The Agency disagrees with the RUC-recommended work RVU of 15.50 and instead proposes a work RVU of 13.29 based on a direct work RVU crosswalk from CPT code 36819 (*Arteriovenous anastomosis, open; by upper arm basilic vein transposition*) with 120 minutes of intraservice time and 283 minutes of total time, which is 2 minutes more than the 281 minutes of total survey time for 434XX.

The Agency fails to provide justification on why the robust survey data from a validated RUC process is ignored in the analyses used to determine the work RVU for this service. A crosswalk based on time alone is not an appropriate justification for any code, especially a new code. In addition, the intensity of this service is not appropriately captured by CMS' crosswalk.
The clinical work, intensity, mental effort, and judgement required for 434XX are higher, along with greater risk due to potential severe adverse events (i.e., esophageal perforation), further increasing the intensity and complexity of the procedure. **We disagree with the flawed crosswalk used by the Agency and urge CMS to accept the RUC-recommended work RVU of 15.50 for CPT code 434XX.**

Placement-Removal of Seton (CPT codes 46020 and 46030)

Global Period Assignment

CPT code 46020 was identified by the RUC Relativity Assessment Workgroup through a screen of 10-day global codes with utilization greater than 1,000 and more than one postoperative visit. CPT code 46030 was added as a family code

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for review. The RUC recommended that both codes be assigned a 0-day global period. A seton is typically placed (CPT code 46020) under anesthesia in an operating room and is typically left in place for 8-12 weeks, or indefinitely in selected cases, with the purpose of providing controlled abscess drainage, thereby allowing all the inflammation to subside and form a solid tract of scar along a fistula tract. Follow-up care of the patient will be variable based on the complexity of the fistula and comorbid conditions (e.g., Crohn's disease). Removal of a seton (CPT code 46030) may not require an E/M follow-up visit related to the removal of the seton or may not require a follow-up visit within 10 days. A 0-day global period allows reporting postoperative care as medically necessary for both procedures. **We appreciate that CMS approved this request for a global period change for these two codes.**

- CPT code 46020 (*Placement of seton*): CMS disagrees with the RUC-recommended work RVU of 3.50 for CPT code 46020 and instead proposes a work RVU of 1.86, as shown in the table below.

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
46020	Placement of seton	3.00	3.50	1.86

The ACS is disappointed that CMS ignored the significant compelling evidence provided regarding the original misvaluation of CPT code 46020, as described below.

- **Evidence was provided about an abnormal survey methodology that was used by the RUC for less than one cycle.** The RUC agreed the historical documents clearly showed a flawed methodology that resulted in an underestimation of work as highlighted by an intraoperative intensity that was nearly zero.

- **Evidence was provided describing a flawed reference service list (RSL) used in conjunction with the abnormal survey methodology being tested by the RUC.** In 2000, the standard RSL for all surveys included codes with each of the different global periods, including 0-day, 10-day, 90-day, and XXX. Only three 10-day global codes were included on the RSL for the survey of CPT code 46020, and all three such codes were Harvard-based. The survey instructions were clear that respondents should be mindful of the global period when selecting a reference code, compelling respondents to choose one of the three Harvard codes with a 10-day global as a reference.

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- **Evidence was provided regarding a flawed global period assignment when this code was newly implemented in 2002.** Although the procedure is a major operation performed under general anesthesia, CMS assigned the code a 10-day global because the Agency believed it would be an office-based service. However, CMS' assumption was incorrect—not only is this procedure almost always performed in a facility, but the RUC also recommends that it no longer be priced in the office setting. CMS' assumption resulted in an incorrect comparison of the CPT code 46020 to other 10-day global minor procedures that were primarily office-based.

Given these numerous irregularities—an incorrect global assignment, a short list of Harvard comparator codes for selection, and a flawed survey instrument—the value for CPT code 46020 cannot be considered valid. We also note that all of these process irregularities have since been corrected through the following actions: (1) there is a recommendation for global period assignment and rationale required in a CPT code change application; (2) RUC survey RSLs almost always only include codes with the same global period; (3) inclusion of Harvard-valued codes on the RSL is strongly discouraged; and (4) more than three applicable codes are included on the RSL.

Instead of considering all the evidence of prior misvaluation for CPT code 46020, along with a change in the typical patient and the procedure itself, CMS proposes a lower value to account for the loss of the postoperative visits due to the change in global period. Specifically, CMS states it is subtracting 2.04 work RVUs from the current work RVU of 3.00 to account for 2 x CPT code 99212 (2 x 0.70 work RVUs) plus 0.5 x CPT code 99238 (0.5 x 1.28 work RVUs). It is not clear how CMS calculated its proposed work RVU of 1.86, as the equation described by the Agency would result in 0.96 work RVUs (3.00-2.04).

We strongly disagree with the application of reverse BBM to subtract work RVUs attributed to E/M visits that were not used to value CPT code 46020. In addition, even though the Agency's calculation is not transparent, it is obvious that when CMS states it subtracted 2.04 work RVUs related to the E/M services, its underlying methodology is intended to remove the CY 2021 increased work RVUs for office/outpatient E/M codes in the same rule that the Agency continues to refuse to update global code values commensurate with the CY 2021 office/outpatient E/M increases.

We also disagree that a value of 1.86 correctly reflects a relative value when compared with the key reference CPT codes 46607 (*Anoscopy with*

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HRA biopsy) and 45380 (*Colonoscopy with biopsy*). Specifically, CPT code 46607 is an office-based procedure with 5 minutes less intra-time, 38 percent less total time, and a work RVU of 2.20, which is 18 percent higher than the CMS-proposed value of 1.86 for CPT code 46020. CPT code 45380 is typically performed under moderate sedation—not general anesthesia—has 2 minutes less intra-time, 35 percent less total time, and a work RVU of 3.56, which is 90 percent higher than the CMS-proposed value of 1.86 for CPT code 46020.

We urge CMS to consider this new information and accept the RUC-recommended work RVU of 3.50 for CPT code 46020. If the Agency continues to disagree with this value, **we request a peer-to-peer review** with the applicable CMS Medical Officers to discuss their rationale and methodology for the CMS-proposed work RVU, the compelling evidence documents for the RUC-recommended work RVU that were provided to the Agency, and the appropriate relativity of the value for 46020 in the fee schedule.

- CPT code 46030 (*Removal of anal seton, other marker*): CMS disagrees with the RUC-recommended work RVU of 2.00 for CPT code 46030 and instead proposes a work RVU of 1.48, as shown in the table below.

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
46030	Removal of anal seton, other marker	1.26	2.00	1.48

The ACS is disappointed that CMS ignored the compelling evidence provided regarding the original valuation. Instead of considering the evidence of prior misvaluation for this legacy (pre-1990) Harvard-based low-volume code, the Agency proposes a lower value to account for the loss of the postoperative visits due to the change in global period. Specifically, CMS states it is subtracting 0.35 work RVUs from the current work RVU of 1.26 to account for the loss of 0.5 x CPT code 99212 (0.5 x 0.70 work RVUs). It is not clear how CMS calculated its proposed work RVU of 1.48, as the equation described by the Agency would result in 0.91 work RVUs (1.26-0.35).

We strongly disagree with the application of reverse BBM to subtract work RVUs attributed to E/M visits that were not used to value CPT code 46030. In addition, even though the Agency's calculation is not transparent, it is obvious that when CMS states it subtracted 0.35 work RVUs related to the

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E/M services, its underlying methodology is intended to remove the CY 2021 increased work RVUs for office/outpatient E/M codes.
We also disagree that a value of 1.48 correctly reflects a relative value when compared with the key reference CPT code 46607 (*Anoscopy with HRA biopsy*) which has a work RVU of 2.20, is a similar office-based procedure, and has slightly less total time. The Agency's proposed value is also significantly less than CPT code 99214, an office-based service requiring only 30-39 minutes of total time compared with 65 minutes of total time related to CPT code 46030. Furthermore, CPT code 99214 includes moderate level of medical decision making and more than 50 percent less total time, making it a suitable comparator code to support the RUC-recommended work RVU of 2.00 for CPT code 46030.

We urge CMS to accept the RUC-recommended work RVU of 2.00 for CPT code 46030. If the Agency continues to disagree with this value, **we request a peer-to-peer review** with the applicable CMS Medical Officers to discuss their rationale and methodology for the CMS-proposed work RVU, the compelling evidence documents for the RUC-recommended work RVU that were provided to the Agency, and the appropriate relativity of the value for 46030 in the fee schedule.

Practice Expense Inputs

For CPT code 46020, CMS proposed to decrease the RUC-recommended PE pre-service clinical staff times to reflect RUC package times for 0-day services instead of 90-day services. The RUC developed packages for preservice clinical staff times to reflect the typical work related to categories of procedures, and in the initial fee schedule, global periods were assigned to surgical procedures based on typical site of service, type of anesthesia, and typical follow-up care. Codes with a 000 or 010 global assignment were considered minor procedures, and codes with a 090 global assignment were considered major procedures. When CPT code 46020 was created in 2002, a 10-day global period was assigned with the assumption that it would be a minor procedure performed in the office. That assumption was incorrect, and as part of the current review for this service, the RUC recommended that CPT code 46020 is a facility-only procedure that will not have office pricing. Even though the original global assignment was 010-days, the RUC acknowledged that CPT code 46020 is a major procedure typically performed in the operating room under general anesthesia, and preservice clinical staff time was assigned commensurate with other major procedures. Under the current review for CPT code 46020, there was also significant discussion by the RUC Practice Expense Subcommittee about whether the preservice clinical staff time should be maintained given the change in global period. The Subcommittee agreed that

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nothing had changed about the preservice clinical staff work and that the clinical staff preservice activities were consistent with major surgical procedures. Therefore, they recommended that the preservice clinical staff time should not change and should reflect the times assigned to major surgical procedures.

The Agency's failure to consider the justification provided to maintain the preservice clinical staff time and instead default to programmatic application of a 0-day global package is disingenuous and calls into question whether there is truly a clinical review conducted when CMS makes valuation recommendations. In this instance, there is no reasonable explanation for assigning 60 minutes of preservice clinical staff time on December 31, 2021, and then decreasing that preservice time to 30 minutes one day later on January 1, 2022. **The ACS intends to coordinate with the RUC to develop an appropriate package for major surgical procedures that have changes made to the global period, but in the interim, we request that the Agency recognize that CPT code 46020 is a major surgical procedure and retain its 60 minutes of preservice clinical staff time.**

For CPT code 46030, CMS proposes to decrease the RUC-recommended PE preservice clinical staff times. The Agency indicates that sufficient evidence was not presented to warrant preservice time in the non-facility setting and proposes no clinical staff time for this setting. We believe there was sufficient information provided to the RUC and CMS to justify preservice extensive use of clinical staff in the office setting. CPT code 46030 is reported 100 percent of the time with no other code when performed in the office setting, meaning that it is not reported with an E/M or any other service on the same date. Therefore, any E/M-related work is included in the work of CPT code 46030. Additionally, in the PE non-facility summary of recommendation form submitted for this code, the preservice clinical staff activities were described in detail. A total of 18 minutes, indicating extensive use, was recommended by the RUC to account for multiple phone calls to the patient, family, and other providers involved in the care of the typical patient, along with follow-up work to arrange for this office-based procedure that will include an anoscopy and other surgical care. More details about these activities are provided in the table below.

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Activity	Time
Complete pre-service diagnostic and referral forms	**5 minutes**: Prior to arrival at the office for the procedure, clinical staff reviews all preservice diagnostic and referral forms to ensure all relevant history and diagnostic information is included.
Coordinate pre-surgery services (including test results)	**3 minutes**: Staff coordinates collection and documentation of imaging/lab results, patient specific information and other relevant patient information from other providers. Enter and record all clinical updates in EHR.
Provide pre-service education/obtain consent	**7 minutes**: Staff reviews procedure, complication risk, process of recovery, and answers patient/family questions.
Complete pre-procedure phone calls and prescription	**3 minutes**: Staff reviews preoperative medication changes and dietary changes prior to this rectal procedure, reviews patient medical status and answers final family/caregiver questions. Enter and record in EHR.

While this procedure is not typically performed in an office setting (i.e., less than 50 percent), there is extensive use of clinical staff when it is safe to do so. **We urge CMS to consider this additional information and accept the RUC-recommended 18 minutes of preservice clinical staff time for CPT code 46030 when performed in the non-facility setting.**

For the facility setting, CMS proposes minimal use of clinical staff. We disagree that this accurately reflects the preservice clinical staff time for CPT code 46030. When a patient is required to undergo this procedure in a facility, it will occur under general anesthesia and all preservice clinical staff activities associated with readying a patient for a major surgical procedure in the operating room are performed. Other similar procedures with 60 minutes of preservice clinical staff include CPT codes 46260-46262 and 46270-46275. **We urge CMS to accept the RUC-recommended 60 minutes of preservice clinical staff time for code 46030 when performed in the facility setting.**

For both CPT codes 46020 and 46030, CMS proposes to refine the direct PE input for CA038 (Coordinate post-procedure services) to 0 minutes from the RUC-recommended 3 minutes to align with 0-day standards instead of 90-day standards. We disagree that CA038 is standard for 90-day codes, and further believe that time for CA038 is specifically not applicable to 10-day or 90-day codes. This activity accounts for office clinical staff phone calls to coordinate transfer of facility information to the surgeon's office medical records, including operative and discharge notes, medication list, other provider correspondence, and imaging or lab results pending at discharge. When

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performed with a 10-day or 90-day procedure, this work is accounted for in CA036 (*Discharge day management*) which does not apply to 0-day global codes. **We request that CMS accept the RUC-recommended time for CA038 for both CPT codes 46020 and 46030 when performed in the facility setting.**

Intracranial Laser Interstitial Thermal Therapy (LITT) (CPT codes 617X1 and 617X2)

Global Period Assignment

In October 2020, the CPT Editorial Panel approved new codes 617X1 and 617X2 to report intracranial laser interstitial thermal therapy (LITT) of lesion for multiple or complex lesion(s). Both major surgical procedure codes were correctly assigned a 0-day global period so that widely variable postoperative multispecialty teamwork can be reported as medically necessary. **We appreciate that the Agency approved this global period for these major surgical procedures.**

- CPT code 617X1 (*Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion*): CMS disagrees with the RUC-recommended work RVU of 20.00 for CPT code 617X1 and instead proposes a work RVU of 19.06, as shown in the table below. CMS believes the RUC partially applied the 23-hour policy to the immediate post service time but not to the work RVU, and states that the 23-hour policy in its entirety should be applied to CPT code 671X1.

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
617X1	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance	NEW	20.00	19.06

We disagree with CMS' proposed work RVU of 19.06 for CPT code 617X1. The surveying specialties adjusted the survey data to conform with the Medicare 23-hour policy that does not allow inpatient services to be included in the time and visit details for a service that is typically performed in the outpatient setting, and then argued that their recommended work RVU of 20.00 was an accurate reflection of the relative work for this code based on magnitude estimation. The 23-hour

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policy was initially implemented in response to the ACS' objection to discounting postoperative inpatient visits by the development of postoperative observation visits for inclusion in services that are more than 50 percent outpatient-based. However, the Agency believes the acuity of a patient with outpatient status is not significant and therefore asserts that the 23-hour outpatient policy should apply. As such, CMS used its formulaic policy of shifting work from E/M visits to immediate postoperative time, reducing the work RVU for all of the codes submitted to the Agency that included inpatient or observation E/M codes.

The RUC rationale submitted to the Agency for CPT code 617X1 included extensive discussion regarding the changes to the survey visit and time data, along with separate and distinct details about the accurate relative value for the service referencing the key reference codes, MPC codes, and additional codes that closely bracket the recommended value of 20.00. The RUC typically uses a survey statistic (e.g., the median or 25th percentile) that reflects relative magnitude estimation or chooses a code with similar work and time to use as a direct crosswalk when valuing a code. In this instance, the RUC agreed that a work RVU of 20.00 was appropriate relative to many references of similar work for both time and intensity. **We urge CMS to accept the RUC-recommended times and work RVU of 20.00 for code 617X1.**

- CPT code 617X2 (*Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)*): CMS disagrees with the RUC-recommended work RVU of 24.00 for CPT code 617X2 and instead proposes a work RVU of 22.67, as shown in the table below.

CPT Code	Descriptor	Current wRVU	RUC-Recommended wRVU	CMS Proposed wRVU
617X2	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)	NEW	24.00	22.67

We disagree with CMS' proposed work RVU of 22.67 for CPT code 617X2. This procedure will not have outpatient status, as patients undergoing this procedure will be admitted to the intensive care unit (ICU)

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and remain in the hospital for at least two midnights. Therefore, we do not believe that the 23-hour outpatient policy applies. The RUC rationale submitted to CMS for CPT code 617X2 included extensive discussion regarding the accurate relative value for the service referencing the key reference codes, MPC codes, and additional codes that closely bracket the RUC-recommended value of 24.00. Further, the Agency has previously approved inclusion of postoperative inpatient E/M CPT codes in the CMS work/time files for codes with 0-day global if the patient status was determined to typically be inpatient (e.g., CPT codes 32601, 32607-32609, 33361-33366, and 33951-33966). CMS has also allowed multiple inpatient E/M CPT codes in the CMS work/time files for codes with ZZZ global assignment (e.g., CPT codes 33257-33259 and 33517-33530). Like CPT code 617X2, all of the codes with 0-day global assignment are major surgical procedures performed on patients who have inpatient status. **As such, we urge CMS to accept the RUC-recommended times, postoperative E/M visit, and work RVU of 24.00 for code 617X2.**

Practice Expense Inputs

As some major surgical procedures may be assigned a 0-day global period, we do not agree that the Agency should steadfastly adhere to an interpretation that clinical staff pre-time packages are inflexible. The RUC has previously agreed that major surgical procedures that have a 0-day global assignment require the same typical preservice clinical staff time as major surgical procedures that have a 90-day global assignment.

There is a significant amount of preservice clinical staff work required prior to surgery for both CPT codes 617X1 and 617X2. These procedures are performed under general anesthesia and require specialized supplies and equipment, preoperative coordination between multiple specialists, and both an operating room and MR suite. These codes were assigned a 0-day global period instead of a 90-day global primarily to accommodate the postoperative multispecialty care that is shared when treating the patient after surgery. The RUC compared the preservice work for these codes to the transcatheter aortic valve replacement (TAVR) procedures and to CPT code 61720 when considering preservice clinical staff work. Detailed information was provided to CMS in the PE summary forms that support the RUC's recommendation. **Until such time that the RUC and the Agency can catch up with changes to global period assignment for major surgical procedures, we urge CMS to acknowledge that the postoperative packaged work related to different global periods is not correlated to preservice clinical staff work.**

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X-Rays at Surgery Add-On (CPT code 74301)

When CPT code 74300 was identified by the RUC for review via a screen of codes never reviewed (CMS/Other Source), low-volume CPT code 74301 was added to the review as a family code. Initially, societies that do not perform this service recommended deletion of CPT code 74301. The ACS disagreed, indicating that the code is still necessary and should not be deleted. The stakeholder specialty societies did not resurvey CPT code 74301 due to its low utilization (2019 Medicare utilization=63) and difficulties in obtaining 30 survey responses from providers with experience performing this service in the past 12 months. Although no survey was conducted, the work RVU and time for CPT code 74301 is directly proportional to the recently-surveyed base CPT code 74300, thereby supporting the current value for CPT code 74301. **We appreciate that the Agency acknowledges this relationship and proposes to maintain the current work RVU of 0.21 for CPT code 74301.**

Revaluing End Stage Renal Disease (ESRD) Monthly Capitation Payment Services (MCP) (CPT code 90954)

In the CY 2021 MPFS final rule, CMS revalued most, but not all, of the ESRD MCP services. The Agency's argument for increasing the values for these 30-day global codes was that they included office/outpatient E/M services, and because such office/outpatient E/M codes increased in value, the ESRD codes should also increase in value.

In our comments to the CY 2021 MPFS, the ACS indicated that not all ESRD-related service codes (e.g., 90951-90962) were based on a building block methodology of discrete E/M services and identified CPT codes 90951 and 90954 as examples of codes that were valued using a crosswalk methodology. We also noted that, for the rest of the ESRD codes, the numbers and levels of visits were not determined as a result of surveys that led to use of the building block methodology; rather, they were developed using magnitude estimation in comparison to the work RVUs of several reference codes. This is evidenced by the fact that the codes do not include visits in the CMS time/visit database, and instead the values are based on total time. We argued support for fair and consistent policy for all global codes, whether the value of the code is based on magnitude estimation, BBM, or a mix of both methodologies. For these specific codes, the RUC survey asked for time and levels of visits, similar to the RUC surveys for global surgical services. The survey times from the ESRD surveys were significantly less than the total times that were assigned to each code, indicating that all of these codes were based on magnitude estimation and additional negotiation at the RUC. **We urge CMS to use a fair and consistent**

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policy for all global codes and believe that if the Agency has decided to the values for ESRD global codes that were developed using magnitude estimation commensurate with the CY 2021 increases to office/outpatient E/M codes, there is no obvious reason as to why all other global codes should not follow the same path and be increased as well.

For CPT code 90954, CMS is compelled by stakeholder arguments that a rank order anomaly was created in the family of ESRD codes when the Agency declined to increase this code for 2021. CMS' rationale was that it was clear the code was crosswalked without a discussion of BBM. Stakeholders have gone directly to CMS to request an increase to the value for CPT code 90954 using a new crosswalk code to correct the anomaly. The Agency agreed and proposes a higher work RVU (20.86) using CPT code 33977 (*Removal of a ventricular assist device; extracorporeal, single ventricle*). However, we wish to highlight that CPT code 33977 has an XXX global period assignment and only includes work on the day of a major surgical procedure (pre/intra/post-service times of 95/180/60). Therefore, not only is the Agency proposing to arbitrarily increase the value for a code that is not under any review and has a 30-day global period using a stakeholder-advocated crosswalk, but the code chosen for crosswalk is a major surgical procedure for work essentially all on a single operative day. We strongly disagree with the proposed crosswalk code and with the process being used to propose an increase for the value of CPT code 90954. **If the Agency or stakeholders believe there is a rank order anomaly, then we request that the process of nominating a potentially misvalued code should be followed—CPT code 90954 should be nominated and the entire code family should be reviewed.** This is important given that the code family: (1) has not been reviewed since 2007; (2) had problems with 2007 survey data and ranking resulting in multiple nonstandard methodologies used to value the codes; and (3) the Agency arbitrarily increased the value for many of these global family codes even though other global codes did not receive the same consideration. **We urge CMS to not change the value for CPT code 90954 and instead nominate this code (and family codes) as potentially misvalued.**

Principal Care Management and Chronic Care Management (CPT codes 99490, 99439, 99491, 99X21, 99487, 99489, 99X22, 99X23, 99X24, and 99X25)

Expansion of Coverage

CMS indicates that, in recent years, it has engaged in efforts to update and improve the relative value of care management and coordination services within the MPFS by identifying gaps in payment and coding. Examples of such

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services include chronic care management (CCM), complex care management, and transitional care management, all of which could have been reported with E/M codes and prolonged services codes, but are now reported with hundreds of new codes that unbundle packaged services such as screening and remote monitoring services. We believe this is an expansion of coverage that has not been accompanied by additional funds to cover such newly-defined discrete work. Further, these unbundled services have never been audited to confirm that there is not duplicative payment for inadvertent reporting of overlapping services. However, for global surgical services, any work by the same provider or a different provider in the same group or specialty within the global period requires a modifier and justification or is otherwise not reimbursed. Similarly, for many years now, the CPT Editorial Panel and the RUC have been monitoring "billed with" codes to determine when different services should be bundled, which almost always results in reduced payment. **We urge CMS to publish data about all of the codes typically billed during the 30-day global at the patient level for care management services.** This information would be helpful to the entire medical community to better understand the effort of caring for complex patients and to provide transparency with respect to reporting unbundled services.

Care Management Work RVUs

In the CY 2020 MPFS final rule, the Agency created two new HCPCS G-codes—G2064 and G2065—representing comprehensive services for a single high-risk disease (i.e., principal care management). For CY 2022, the RUC resurveyed the CCM code family, including complex chronic care management (CCCM) and principal care management (PCM), and added five new CPT codes to the family. The Agency reviewed the RUC-recommended values for the 10 codes in this family and proposes to accept the RUC-recommended work values. The Agency believes that proposing to accept these updated values is consistent with its goal of ensuring continued and consistent access to these crucial care management services and acknowledges CMS' longstanding concern about undervaluation of care management under the MPFS.

The ACS agrees that focused patient care management can help create a healthier society, and we support any effort that can bring about such a change. However, we do not agree that changes should be made to increase reimbursement to any specific sector of medicine without sufficient supporting evidence. With respect to this family of 10 care management codes where CMS proposes to accept the RUC recommendations without discussion or objection, we are deeply concerned that CMS continues to ignore relativity and data when it comes to primary care services because there is a belief about undervaluation of primary care specialties compared with medical and surgical

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specialists. We note that CPT code 99490 was reviewed in 2014 and was originally written as a single code for reporting "at least 20 minutes" of CCM services. For CY 2022, this code is being split into primary CPT code 99490 for physician supervision of the first 20 minutes of clinical staff time and add-on CPT code 99439 for physician supervision of each additional 20 minutes of clinical staff time. When CPT code 99490 was previously surveyed, there were 338 responses to the survey and the RUC recommended 15 minutes of physician supervision time for 20 minutes of clinical staff time. Although this code had 4.1 million claims in 2019, the surveying specialty societies only collected 84 surveys. Only 4 (4.7 percent) of these surveys were from internal medicine and family practice, even though such specialties represent 71 percent of the total 4.1 million Medicare utilization. CMS does not discuss this discrepancy of fitness-to-rate nor does it question why the physician supervision time (25 minutes) is now greater than the clinical staff time (20 minutes). For any surgical code that is split, for example, into a simple and complex procedure, the Agency has always applied budget neutrality, thereby reducing the work RVU for both codes. However, in this instance, not only is budget neutrality not implemented or even discussed, but the original code has been increased by 64 percent based on two-thirds less surveys where most of the surveys came from specialties that do not typically provide the service. **Although CMS is only seeking comment on whether keeping professional PCM and CCM at the same value creates an incentive to bill CCM instead of billing PCM when appropriate, we urge the Agency to critically look at all of the work RVU values and survey times for this family of codes due to the physician/staff time discrepancies. We also urge the Agency to audit claims data during the 30-day billing period for these and other similar codes to confirm no overlap of work.**

Principle Care Management Work RVUs

CMS proposes to adopt the RUC recommendations for CPT codes 99X22-99X25. We disagree with the premise of these codes, which we believe unbundles work from other reportable services at the same time that the other services can be reported. We also believe the values for these codes are overstated. For example, we disagree with the proposed work RVU of 1.45 for 32 minutes of physician PCM services over a 30 day period for a patient who has a single chronic condition. The intrawork intensity and work per unit time (0.045) places the intensity of this work above a new patient E/M office visit requiring high medical decision making (MDM) (CPT code 99205; work RVU=0.040). The work over 30 days is described as requiring development or revision of a disease-specific care plan, but we do not understand how that can be accomplished outside of an E/M service. The work also describes frequent adjustments in a medication regimen; however, it is unlikely that this would

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typically occur within a 30-day span of time, or that this work could not be reported with other digital/audio codes. The code descriptor also describes ongoing communication and care coordination between all practitioners furnishing care; however, we do not understand how this multidisciplinary care should be reported for work related to this single chronic condition code, since only the single high-risk disease is being addressed. If other comorbidities and diseases were being addressed, then this work should be reported with complex care management codes. As such, PCM is currently reportable with many other patient care codes and valuing this nebulous work more than the highest office E/M visit intensity is not appropriate. **We urge CMS to reconsider whether these PCM codes are valid discrete services and to develop an audit mechanism to determine how this new unbundled coding paradigm works in the real world and whether it improves efficiency of care.**

Evaluation and Management Visits

Split/Shared Visits

CMS currently refers to a "split" or "shared" service as specific to E/Ms and as one that is performed by both a physician and a nonphysician practitioner (NPP) who are in the same group. In the office setting, current rules allow for the physician to bill for the service when portions of the service are performed by an NPP under the rule set for "incident to" services. In the facility setting, there is no provision for "incident to" billing, nor are there payments to NPPs for delivering this service with a physician. Medicare currently provides payment only to the physician or NPP who personally performs all elements of the facility service. In response to areas not addressed by the CPT Editorial Panel, CMS proposes to define split/shared services as an E/M visit in the facility setting that is performed in part by both a physician and an NPP who are in the same group in accordance with applicable laws and regulations.

As an overarching comment, we urge CMS not to make these changes to the billing rules for E/Ms provided in facilities at this time. The CPT Editorial Panel has approved revisions to the code descriptors for inpatient codes and related guidelines, which will be effective for CPT 2023. Changing the Medicare reporting instructions for 2022 in ways that may or may not be consistent with the CPT code set changes that will go into effect the following year will be confusing for physicians, NPPs, billers, and coders.

- Same Group: CMS proposes that the physician and NPP must be in the same group for the physician and NPP to bill for a split or shared visit, and CMS seeks comment on whether it should further define group for these purposes. CMS notes that defining a group as tax identification number

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(TIN) could create a group that is too large to assume that all the practitioners work closely enough to allow split/shared billing. We agree that defining a group by TIN has its challenges. A TIN can be quite large and encompass many different specialties. In an employed model, advanced practice practitioners (APPs) are commonly managed by the practice with the salary functioning as a pass through. They tend to be part of the same TIN, but not always. The use of Medicare specialty is another approach, but APPs may not declare a Medicare specialty. **A combination of TIN and Medicare specialty could be an option as well to capture the services from APPs that are truly working closely enough with the physicians in the group to share services.**

- Substantive Portion: CMS maintains that only the provider who performs the "substantive portion" of the visit (i.e., more than half of the total time spent by the physician and NPP performing the visit) may bill for the visit. However, the practitioner providing the substantive portion of the visit can select the level for the split or shared visit based on MDM. **Defining the "substantive portion" of the visit using time is not always appropriate, especially when the code level selection is based on Medical Decision Making (MDM) and not time.** In certain clinical scenarios, the determination of the "substantive portion" of the visit should not be based purely on time, and MDM should instead be the deciding factor of "substantial" rather than length of documentation or time. For example, an APP could spend considerable time gathering information for the physician to review, or accomplishing other similar activities, while the surgeon may come in, make several risky decisions, mobilize a whole operative team, decide on which incision or approach to use, and then prepare the patient for rapid exploration. These activities of the surgeon could take place in a short time span, but these are the critical decisions that make-or-break survival and lack of morbidity in a patient. In addition, some APPs tend to document more compared to physicians, which could inappropriately justify billing at a higher time. Finally, current CPT E/M Guidelines are clear that time is a factor only when time is being used to select the appropriate level of service for which time-based reporting of shared or split visits is allowed.

- Qualifying Time: CMS proposes a list of activities that could count toward total time for purposes of determining the substantive portion of a split/shared visit. This list, which is based on the current CPT E/M Guidelines for office or other outpatient E/M services, includes the following (regardless of whether they involve direct patient contact):
  - Preparing to see the patient (for example, review of tests)
  - Obtaining and/or reviewing separately obtained history

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- Performing a medically appropriate examination and/or evaluation
- Counseling and educating the patient/family/caregiver
- Ordering medications, tests, or procedures
- Referring and communicating with other health care professionals (when not separately reported)
- Documenting clinical information in the electronic or other health record.
- Independently interpreting results (not separately reported) and communicating results to the patient/family/caregiver
- Care coordination (not separately reported)

As stated above, we have concerns with using time for determining the substantive portion of a split/shared visit. A poorly informed clinician could spend more time coming to a wrong decision that is dangerous for the patient, while a smart and efficient clinician could take less time to arrive at the right medication, diagnostic test, or other treatment(s). Because MDM is the substantive physician work, MDM should take precedence over recording activities and the time spent by the various clinicians. Also, we request clarification on situations where a physician is participating in some of the activities on this list, but supervising APPs remotely. Specifically, we question if remotely supervised services would count as split/shared visits.

It is a mistake for CMS to move forward with this proposal for CY 2022, since these activities are currently only related to office/outpatient E/M visit codes. For example, only office/outpatient E/M codes describe "Performing a medically appropriate examination and/or evaluation." All other E/M codes still require specific levels of examination. We understand that there are changes approved for other E/M codes for CPT 2023. **We urge the Agency to delay changes to split/shared visit to reduce reporting confusion.**

We also draw CMS' attention to and question the time parameters for these services. For example, the time in the CMS time file for office or other outpatient visit E/Ms include three components (Pre=3 days before; Intra=day of; and Post=7 days after). However, for facility E/M codes that are not reported as "other outpatient," the current code descriptors typically state "per day" of care. **What are the time parameters for capturing qualifying time for these activities under this new policy for each family of E/M codes?**

CMS seeks comment on whether it should create a separate list of qualifying activities for split/shared emergency department visits. **We do not believe there are "visits" for emergency medicine services, rather this work is more similar to the inpatient care services, which are "per day" codes.** Further, much of the emergency department work is performed by NPPs based

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on a team model and CMS should consider establishing code descriptors to better reflect this care model.

- Application to Prolonged Services: CMS is proposing to change its policy to allow a practitioner to bill for a prolonged E/M visit as a split or shared visit. **This is yet another area where the Agency's proposal will be problematic and will cause confusion due to expected code descriptor and guideline changes for CPT 2023.** Changing the Medicare reporting guidelines for CY 2022 in ways that may or may not be consistent with the changes that will go into effect for CPT 2023 in the following year will be confusing.

- Documentation Requirements: This proposed rule does not speak to how providers should document the qualifying time that was used to determine whether the physician or the NPP is the billing provider. Such information is important for providers to have in order to avoid inappropriate or incorrect billing. In instances where MDM is used to select the level of code to be billed, time may not necessarily be recorded. **The qualifying time requirement will be difficult to audit and will create more administrative burden because it is adding a reporting requirement that did not previously exist.**

Critical Care Visits and Global Surgery

CMS proposes to bundle critical care visits with procedure codes that have a global surgical period. CMS' first rationale is that critical care visits are included in some 10- and 90-day global codes. CMS' second rationale is that the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requirement to collect data on the number and level of postoperative visits provided within 10- and 90-day global periods is ongoing. CMS refers to previous concerns related to lack of sufficient data on the number and level of visits typically furnished during a global period, questions whether CMS will be able to adjust values on a regular basis to reflect changes in the practice of medicine and health care delivery, and expresses concern about how global payment policies could affect services that are actually furnished.

CMS should not finalize this policy as proposed. We strongly oppose a proposal that would prevent surgeons from being able to appropriately use modifier -24 (*Unrelated E/M Service During Post-Operative Period*) or modifier -25 (*Significant Separately Identifiable E/M Service on the Same Day of a Procedure or Other Service*). Not only do CMS' rationales not support this policy, but this policy will prevent surgeons who provide both operative and critical care services from being fairly reimbursed for their time

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spent legitimately caring for some of their sickest patients in and out of the operating room. CMS should instead maintain the current provision in the Medicare Claims Processing Manual that specifically allows modifiers -24 and -25 to be used to indicate that the critical care service can be billed when unrelated to the procedure. This section states:

> *Critical care services provided during a global surgical period for a seriously injured or burned patient are not considered related to a surgical procedure and may be paid separately under the following circumstances.*
>
> *Preoperative and postoperative critical care may be paid in addition to a global fee if:*
> - *The patient is critically ill and requires the constant attendance of the physician; and*
> - *The critical care is above and beyond, and, in most instances, unrelated to the specific anatomic injury or general surgical procedure performed.*
>
> *Such patients are potentially unstable or have conditions that could pose a significant threat to life or risk of prolonged impairment.*
>
> *Modifier -24 (post-operative) or -25 (same day pre-operative) is used to indicate that the critical care service is unrelated to the procedure.*[8]

CMS' Rationales Are Not Sound

CMS states that "because critical care visits are included in some 10- and 90-day global packages, we are proposing to bundle critical care visits with procedure codes that have a global surgical period." [9] This rationale is not valid. **If critical care visits are included in *some* global codes, that has no bearing on whether critical care visits should be included in the remainder of the 10- and 90-day global codes, let alone in *all* global codes.** Few global codes include critical care visits because few procedures require critical care

[8] Centers for Medicare & Medicaid Services. (2018). *Medicare Claims Processing Manual, Chapter 12, Section 40.1*. U.S. Department of Health and Human Services. Retrieved from https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf

[9] Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements, 86 Fed. Reg. 39211 (Proposed Rule July 23, 2021)

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services. This policy would presume that because *a few* 10- and 90-day global services typically require critical care services, then *all* 10- and 90-day global procedures require critical care services, which is not true. Whether or not 10- and 90-day global codes require postoperative critical care related to the operation is discussed on a code-by-code basis as part of the AMA/RUC deliberations on valuation of codes, and only included if the typical patient requires critical care services directly related to the procedure.

CMS' second rationale, in reference to the MACRA data collection on number and level of post-operative visits, is that "because this work is ongoing, we are proposing to bundle critical care visits with procedure codes that have a global surgical period."[10] CMS also cites "lack of sufficient data on the number of visits typically furnished during the global periods" as support for the ongoing MACRA data collection**.** [11] Not only does this rationale not support the proposal to bundle critical care into visits with global codes, it is a strong justification for *allowing* critical care services to be billed separately when the use of modifiers -24 and -25 is appropriate. **If there is a lack of sufficient data on the number and level of postoperative visits as well as ongoing work to study these visits, CMS should not preemptively assume that it is appropriate to bundle all critical care into 10- and 90-day global surgical packages.**

Undervaluation of Surgical Care

This policy grossly misvalues/undervalues the care provided by surgeons and surgical teams to the sickest patients in the hospital, some of whom become sick unpredictably. **Specifically, this policy undervalues the ICU care required for some post-surgical patients and undervalues the expertise of those intensivist surgeons caring for the most complex patients.** As described above, most surgical patients do not require ICU care, and ICU care is not included in the value of most 10- and 90- day global codes. But some patients are either already critically ill when requiring surgery or become critically ill unpredictably after surgery. In these cases, surgeons and surgical intensivists are best equipped to manage the critical care services for these patients postoperatively. The surgeons are most familiar with their patient's case and their postoperative course. They are also most familiar with complex operations, the impact of comorbidities, and surgeons have the best skillset to identify and manage postoperative issues as well as recognize the expectations/pitfalls of surgery. The critical care that surgeons provide accounts for the constant attention, availability, interaction, and coordination

[10] *Id.*
[11] *Id.*

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with multiple other specialties that may be required for these patients. The result of this level of care is that high intensity staffing (ICUs where intensivists manage or co-manage all patients) versus low intensity staffing (where intensivists manage or co-manage some or none of the patients) is associated with 30 percent reduction in hospital mortality and a 40 percent reduction in ICU mortality.[12] We are concerned that this proposal, which would deny reimbursement for this vital work, reveals CMS' lack of understanding of the clinical environment and the complexity of care of patients today.

Critical Care in Various Settings

Surgical teams and surgical intensivists are aggregated in major trauma centers and teaching hospitals. Today's care models occur in these large centers that take care of the most complex patients, and appropriately incorporate surgeons into the ICU team. The Leapfrog Group's ICU initiative recognized this ICU model as a significant patient quality improvement and, in fact, recommended it as a requirement.[13] In these large centers, the doctors can all be in the same physician group or faculty plan leading to a team approach to the work. In such cases the surgeons and/or their group partners perform both global surgical procedures as well as provide critical care that is unrelated to the procedure.

For example, it is not uncommon for practices in these large centers to have a Medical ICU team as well as a surgical critical care team all in the same physician group. Similarly, many severely injured patients are unstable and managed non-operatively in the surgical ICU for their multiple trauma. It is not uncommon for a member of the surgical team to perform a surgical procedure with a global period, such as tracheostomy or laparotomy, on a trauma patient who had not previously required surgery, and then surgical team members will continue to provide critical care services, unrelated to the tracheostomy or laparotomy, until the patient is stabilized. **Eliminating appropriate separate billing for critical care services, simply because there was a procedure performed on the patient by one of their partners, would be unfair to those surgeons who provide these needed services to critically ill patients.**

Outside large centers in mid-sized regional hospitals, the ICU census will be smaller but nonetheless managed by board certified intensivists whether they be medically trained or surgically trained. In these settings the surgical critical

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[12] Pronovost PJ, Young T, Dorman T, Robinson K, Angus DC. (1999). Association between ICU physician staffing and outcomes: a systematic review. *Crit Care Med*.; 27:A43.
[13] Leapfrog Group. (2021). *Factsheet: ICU Physician Staffing*. https://preview2021.ratings.leapfroggroup.org/sites/default/files/inline-files/2021%20IPS%20Fact%20Sheet_3.pdf.

care is heavily dependent on the expertise of the surgeon. Their ability to manage these patients in the ICU with or without medical colleagues is certainly in the best interests of quality patient care.

Finally, in smaller hospitals where no intensivists are on staff and a surgical patient requires intensive care, it will largely be in the setting of waiting for transfer to a higher level of service. It is not unusual for transfer to take 24 to 48 hours to complete. In these situations, clearly it is in the best interest of the patient for the surgeon to provide critical care services without concern for unfair reimbursement.

There are approximately 5,000 surgeons who are board certified in surgical critical care through the American Board of Surgery. For most of these surgeons, "critical care" or "intensivists" is their secondary Medicare designation, not their primary. The secondary Medicare designation is not captured through billing, so it is likely that CMS does not have data on the number of surgical intensivists providing critical care and the number of services they provide. Therefore, it is possible that CMS does not fully understand the impact that this policy will have on surgical intensivists.

Clinical Examples

The table below lists clinical examples where surgeons provide necessary critical care services for which reimbursement would be eliminated by this policy.

Clinical Examples of Critical Care Cases That Should Not Be Bundled Into The Global Period	
• **Critically ill patients that require a global surgical procedure in addition to unrelated critical care services**	
1.	A patient with multiple co-morbidities presents in hemorrhagic shock from a ruptured splenic artery aneurysm. The general surgeon performs an exploratory laparotomy and splenectomy with temporary abdominal closure. Patient is returned to OR in 24 hours for removal of packing and abdominal closure. The patient requires complex postoperative critical care for the next 10 days for ventilation, correction of coagulopathy, and management of pre-existing portal hypertension and encephalopathy related to known cirrhosis. This surgical critical care is provided by the same surgeon/team that performed the operative procedure.
2.	A patient presents in delayed fashion in septic shock with a perforated duodenal ulcer. The general surgeon performs graham patch closure of the ulcer and then provides critical care services for management of septic shock.
3.	A patient with perforated colon cancer presents to ED with septic shock, acute respiratory failure, and acute kidney injury (AKI). Patient undergoes a

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	colectomy for the perforated colon, but also requires septic shock management, ventilator management and continuous renal replacement therapy for AKI. An ICU team, including the general surgeon who performed the colectomy will be providing all the critical care support for the patient that is unrelated to the operative procedure.
4.	Burn surgeons also provide ICU care and operate on nearly all their ICU patients multiple times during their hospital stay. They would be perpetually in the global period and not able to bill for the very labor-intensive ICU care that is not related to the procedures for burn treatment.
5.	A patient with intraabdominal trauma and an open abdomen due to sepsis requires trips back to the OR on a frequent basis for washouts, debridement, etc. This is all done by the general surgeon, who also attends to and cares for the critically ill patient in ICU post-op, providing critical care services, which typically include blood transfusions and treatment of shock.
6.	A multi-trauma patient receives complex ventilator support from a trauma surgeon after exploratory laparotomy for a crush injury.
7.	A patient has a pulmonary contusion, chest trauma, closed head injury and orthopedic injuries. This patient goes to OR for orthopedic fixation and then the ICU surgeon from the same group takes the night shift and spends time in the ICU stabilizing the patient.
• **Patient becomes critically ill due to an unrelated issue or unexpected postoperative course following a procedure that warrants escalation of care**	
8.	The general surgeon performs a laparoscopic appendectomy. On postoperative day 1 the patient has an aspiration event requiring critical care including intubation and management of mechanical ventilation.
9.	Patient with septic shock due to a gangrenous gallbladder, underlying diabetes mellitus had an open cholecystectomy, developed AKI, requiring continuous renal replacement therapy, on top of chronic kidney disease and continued respiratory failure.
10.	A postoperative pancreaticoduodenectomy patient ruptures a gastroduodenal artery pseudoaneurysm and requires resuscitation for hemorrhagic shock and follow-up critical care services by the surgical ICU team.

In summary, we urge CMS not to finalize this policy as proposed, which will prevent surgeons from being properly and fairly reimbursed for providing critical care services to their patients. **Instead, CMS should continue to allow physicians to bill for critical care services within a global period using modifiers -24 and -25, when appropriate.** CMS has not presented a rationale for why this proposed policy is needed. The policy provides no benefit and would cause potential harm to surgical patients and have significant impact on the surgeons who care for them.

Payment for the Services of Teaching Physicians

Stakeholders have asked CMS how teaching physicians who involve residents in furnishing care should consider time spent by the resident in selecting the

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office/outpatient E/M visit level under the current policy that allows visit level to be selected based on time or MDM. CMS proposes that when total time is used to determine the office/outpatient E/M visit level, only the time that the teaching physician was present can be included. CMS also proposes that under the primary care exception (services furnished in certain teaching hospital primary care centers for certain services of lower and midlevel complexity without the teaching physician present), only MDM can be used to select the office/outpatient E/M visit.

Generally speaking, we support the use of MDM for the work that surgeons do. In many cases, the amount of time a surgeon spends on a case could be small relative to the importance of the MDM involved. **We also ask for clarification on the part of the definition related to "teaching physician was present."** Specifically, we question if "present" means present in the same room as the resident during the visit, or present with the patient, or present somewhere nearby. In addition, we ask for clarity on what activities of the teaching physician count toward the time the teaching physician was present, and question if face-to-face time is required or if non-face-to-face time as described in CPT guidelines count. With respect to the primary care exception, we agree that only MDM should be used to select the lower/midlevel code given that residents in training may require more time than is reflected in the code descriptor to furnish a visit that has a low-level of MDM. We also urge CMS to not make changes or clarifications to this policy for CY 2022 given that CPT could make substantial changes as it continues to review and revised the E/M code set for CPT 2023.

Office Visits Included in Codes with a Surgical Global Period

We continue to voice our disappointment that CMS has failed to incorporate the RUC-recommended work and time incremental increases for the revised office/outpatient visit E/M codes into the global codes. CMS has failed to address this issue in both the CY 2021 and CY 2022 MPFS rules. While CMS did finalize adjustments for other bundled services, such as maternity codes, in the CY 2021 MPFS, organized medicine has been united in its recommendations that CMS incorporate the incremental revised office/outpatient E/M values into all of the 10- and 90-day global surgical package codes, as evidenced by the many comment letters and meetings over the past several years.

The proposed 3.75 percent reduction to the CY 2022 conversion factor will further add to cuts that many physician specialties have been experiencing for years. **We reiterate that it is inappropriate for CMS not to apply the RUC-recommended changes to global codes**. To do otherwise will continue to:

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- Disrupt the relativity in the fee schedule: Applying the RUC-recommended E/M value increases to stand-alone E/Ms, select global codes (e.g., monthly end-stage renal disease and bundled maternity care), and select bundled services (e.g., monthly psychiatric management), but not to the E/Ms that are included in the global surgical package will result in disrupting the relativity between codes across the MPFS, which was mandated by Congress, established in 1992, and refined over the past 27 years.

  In 1991, a CPT revision of the E/M codes required Harvard and CMS to add work to global codes for the E/M. CMS assigned to the global codes what the Agency believed to be the equivalent to the work value for the discrete E/M codes. But then following this assignment, the work for the discrete E/Ms was increased slightly in the first fee schedule in 1992 and then increased again in 1993. These two changes by Harvard in 1991 and CMS in 1992 were never translated back to the global codes. So from the very beginning of the fee schedule, the postoperative E/M work relative value was discounted by 15-20 percent. The full value of the E/Ms has never been added back to global codes because the RUC doesn't use the BBM. But each time that E/Ms increased and CMS adjusted the global code values, only the incremental increase was applied, maintaining relativity. In summary, since the inception of the fee schedule, the E/Ms in the global codes have been discounted, but the original relativity has always been maintained. By not increasing the global by applying the incremental increase, the Agency has essentially established two separate fee schedules that are no longer relative.

- Create specialty differentials: Per Medicare statute, CMS is prohibited from paying physicians differently for the same work, and the "Secretary may not vary the . . . number of relative value units for a physician's service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician."[14] Failing to adjust the global codes is tantamount to paying some doctors less for providing the same E/M services, which is in violation of the law. In the CY 2021 MPFS proposed rule, CMS pointed to the method of valuation (i.e., building block vs. magnitude estimation) for a rationale as to why some bundled services should be increased in value to reflect the revised office/outpatient E/M values, while global codes should not. However, this statutory prohibition on paying physicians differently for the same work applies regardless of code valuation method and the incremental increases should apply to all physicians.

[14] 42 U.S. Code §1395w-4(c)(6).

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- Ignore recommendations endorsed by nearly all medical specialties: The RUC, which represents the entire medical profession, voted overwhelmingly (27-1) in 2019 to recommend that the full incremental increase of work and physician time for office visits be incorporated into the global periods for each CPT code with a global period of 10-day, 90-day, and MMM (maternity). The RUC also recommended that the practice expense inputs should be modified for the office visits within the global periods. In the CY 2021 MPFS, CMS used the RUC recommendation as part of the rationale for proposing to increase the values of the maternity services codes and select other bundled services, but not the global bundled codes.

Again, we strongly urge CMS to apply the RUC-recommended changes to the E/M component of the global codes to maintain the relativity of the fee schedule congruent with the revaluation of the office/outpatient E/Ms. While we believe the Agency should have made the adjustments to the globals in CY 2021 rulemaking rather than in CY 2022, we would highlight that it would not be without precedent to address the valuation of the global codes in the subsequent year. After changes were made as part of the first Five-Year Review of the MPFS, CMS (formerly the Health Care Financing Administration (HCFA)) initially declined to apply the E/M increases to the globals. However, the following year, in the CY 1998 MPFS final rule, the Agency directly stated, "Upon further examination of this issue, we are increasing the work RVUs for global surgical services to be consistent with the 1997 increases in the work RVUs for evaluation and management services."[15]

As we have consistently held, it has been the Agency's policy to make these changes to the global codes, and it would not be without precedent to make them in the year subsequent to the revaluation of the E/Ms. We implore the Agency to follow its own precedent and resolve this issue.

Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests

Section 122 of the Consolidated Appropriations Act (CAA) of 2021, Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amends section 1833(a) of the Social Security Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is

[15] Medicare: Physician Fee Schedule for Calendar Year 1998; Payment Policies and Relative Value Unit Adjustments and Clinical Psychologist Fee Schedule, 42 C.F.R. § 400 (1998).

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furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test.[16] Currently, the addition of any procedure beyond a planned colorectal cancer screening test (for which there is no coinsurance), results in the beneficiary having to pay coinsurance. The reduced coinsurance will be phased in beginning January 1, 2022.

We thank CMS and Congress for addressing surprise medical bills related to colorectal cancer screening and diagnostic services, and support the elimination of coinsurance for such services to reduce out-of-pocket costs for Medicare beneficiaries. We encourage the Agency to consider how to address additional cost-sharing issues that may arise as new colorectal cancer screening technologies (e.g., Cologuard) continue to emerge and increase in Medicare utilization relative to flexible sigmoidoscopies and screening colonoscopies.

OTHER PROVISIONS OF THE PROPOSED RULE

Appropriate Use Criteria for Advanced Diagnostic Imaging

Section 218(b) of the Protecting Access to Medicare Act (PAMA) directed CMS to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. There are four major components of the AUC program, each with its own implementation date: (1) establishment of AUC by November 15, 2015; (2) clinical decision support mechanisms (CDSMs) for consultation with AUC by April 1, 2016; (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017; and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017.

Due to numerous delays in implementation, CMS did not require ordering professionals to consult AUC using CDSMs or furnishing professionals to report information on consultation by January 2017. On January 1, 2020, the program began with an educational and operations testing period for the claims-based reporting of AUC consultation information. In response to the COVID-19 pandemic, the educational and operations testing period was extended through CY 2021, and CMS proposes to further delay implementation of the AUC program claims processing edits and payment penalty phase to begin the latter of January 1, 2023, or the January 1 that follows the declared end of the PHE.

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[16] Pub. L. No. 116- 260

In recognition of the ongoing pandemic, during which the medical community is already dealing with tremendous financial and care delivery issues due to COVID-19, we support CMS' proposed penalty phase delay to allow time to address key workflow challenges and costs associated with AUC consultation and reporting requirements. During the PHE, neither provider nor government resources should be diverted to putting in place the systems and processes necessary to implement the AUC program.

The ACS also continues to have concerns about physicians' ability to meet CMS' AUC program requirements post-PHE. While the Agency asserts that using coding structures that are already in place will ease reporting processes, it has not specified what G-codes or modifiers would be required for reporting. Further, this approach has already been rejected by the National Uniform Claim Committee (NUCC) and National Uniform Billing Committee (NUBC), which stated that the use of G-codes and modifiers would be administratively burdensome and that all options to report AUC data will be costly and operationally difficult for physicians to implement. If CMS finalizes its AUC proposals without additional delay, physicians will have limited time to determine how to comply with these policies, assess available CDSMs with such policies in mind, select the CDSM most appropriate for their services and practice, integrate the CDSMs into their practices—including with their EHRs and billing systems (assuming G-codes and modifiers are finalized at the same time)—and train clinicians on their use.

Given the substantial burden and practice expenses that we anticipate the AUC requirements will create, the College believes that it is important that physicians are afforded the opportunity to adjust to the program in a thoughtful and deliberate manner that would allow for interoperability (i.e., integration of CDSMs into practices' EHRs and practice management systems). Practices should also have the opportunity to develop solutions for data exchange between the ordering and furnishing physicians in order to leverage health information technology to reduce burden. To accommodate all of the above, we believe it will be important for CMS to allow for gradual implementation of the AUC requirements. Under such a policy, CMS would pay claims for advanced diagnostic imaging services regardless of whether the required information about the AUC consultation is included in the claim. In addition, it is critical for CMS to test that submitted claims with the AUC information are correctly processed before the program is implemented. As CMS moves toward full accountability under the AUC program, we also recommend that CMS carefully consider the extent to which the Agency can continue to align the goals and requirements of this program with quality reporting programs and alternative payment models in order to minimize burden and limit duplication of effort.

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ADVANCING TO DIGITAL QUALITY MEASUREMENT AND THE USE OF FAST HEALTHCARE INTEROPERABILITY RESOURCES (FHIR) IN PHYSICIAN QUALITY PROGRAMS – REQUEST FOR INFORMATION (RFI)

As part of CMS' Meaningful Measures Framework, the Agency aims to transition to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. To plan this transition, CMS asks for input on various areas that will provide pathways for greater quality data collection and advanced interoperability.

In general, the ACS is supportive of using digital tools to capture the full scope of patient data to inform patient care and quality improvement efforts, but as stated in our following comments, the **ACS believes that the current structure of CMS programs forces physicians to chase metrics for payment purposes instead of implementing quality programs that leverage digitally derived knowledge to drive continuous quality improvement. We believe that when planning the transition to digital quality measures, CMS should not focus solely on how to advance to digital quality measures that only account for single metrics.** Single metrics offer little value to patients when they are seeking high-quality care and little value to physicians for driving quality improvement cycles. Creating a digital framework to aggregate data for single metrics will make it easier and less burdensome to collect data but if the measurements do not drive meaningful quality improvement or appreciate the comprehensive patient journey and patient goals, we are left with the same problem we have now. Instead, **we suggest focusing this transition on utilizing digital tools to enhance more comprehensive quality improvement programs that have proved to drive improvements in care.**

Quality improvement using digital services should focus on supporting a digital services landscape that goes beyond simply aggregating quality metrics. Instead, it should leverage digital services by building knowledge around a patient's care pathway through aggregating clinical care on open standards-based platforms that can ingest data from numerous sources. These digital services are nascent and hold great promise to enhance knowledge sharing around care to enable the following services:

1. Support the use of CDS to make clinical guidelines and pathways available as a digital service through platforms that are not constrained by proprietary efforts from EHRs.
2. Support the ability to gather condition or procedural cohort data for outcomes reporting and to assess conformance with guidelines-based care.

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3. Support data aggregation and analytics for near real-time research and clinical trials for expanding sample sizes in randomized clinical trials (RCTs) and observational studies.
4. Support quality metrics payors seek for their payment incentive programs in a patient centered manner.

These open architecture platforms are essential to expand medical knowledge management and optimize care. By using open standards-based platforms, data can be assembled for the individual patient (not the single EHR level) to build a patient perspective inside HIEs and allow for more shared and coordinated care. This architecture can meet and exceed payor needs for quality metrics, as well as enrich clinical knowledge. Retooling the healthcare industry for digitally supported knowledge enhancements takes considerable capital investment. If Medicare continues to distract the health informatics development and operations (DevOps) by focusing merely on metrics tied to payment activities, these capital needs to support better outcomes will be delayed. **We encourage the Agency to think more broadly about the underpinnings of digital healthcare so that the four aspects of care outlined above—CDS, cohort analytics, research, and payor metrics—are recognized in the same capital plans.**

Furthermore, digital tools that enhance quality programs or enable payor metrics should be engineered with an architecture that can be implemented and scaled on an open standards-based platform that deploys open source, standards-based infrastructure, such as FFHIR, HL7 V2 messaging, etc. The Amazon Health Lake[17] is an example of this architecture that offers such engineering and an array of advanced digital services, such as natural language processing and more.

Additionally, as CMS continues to require that certain digital services be implemented in EHRs, we ask that they consider all aspects of implementation, including cost to the system. Many EHR vendors have added these required digital services to their systems at a cost beyond reason for an open market. Their proprietary, closed systems still have not fulfilled the intent of the Congressional efforts to overcome the bidirectional impacts of EHR vendor data blocking. To fully reduce the burdens of implementation, the digital environment needs an open marketplace that can absorb these costs. It is not enough to reduce clinical burden of data aggregation if the fiscal burden of constrained, proprietary vendor actions consumes more and more precious healthcare resources. In addition to affordable digital services, as data flows from the EHRs into clinical analytics, the EHRs should also provide a

[17] Amazon Health Lake. Retrieved from: https://aws.amazon.com/healthlake/

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reasonable and affordable environment for data to become available to the EHR from other sources, such as the platforms and data lakes mentioned above. Without this ability, the EHRs will continue to data block elements of care.

Definition of Digital Quality Measures

CMS requests input on developing a definition of a digital quality measure (dQM). The Agency considers defining a dQM "as a software that processes digital data to produce a measure score or measure scores." They also describe possible data sources for dQMs as:

- Administrative systems,
- Electronically submitted clinical assessment data,
- Case management systems,
- EHRs
- Instruments (such as, medical devices and wearable devices),
- Patient portals or applications,
- HIEs, and
- Registries, etc.

To support a "quality program" framework as described in the MVP sections, we suggest that CMS change its emphasis from aggregating data with dQMs that focus on single metrics to developing a definition for the digital enhancement of quality improvement programs. Regarding the data sources that can be used to gather EHI, we suggest that CMS expand this list further to include not only case management systems, but case management software as well, such as BPM+ Health. In addition, we believe that patient portals and applications should be considered separate data sources, instead of grouping them together. Further, we ask that CMS include other patient-centered platforms, such as those hosted by specialty societies.

The ACS believes that digital tools will be an essential part of the continued enhancement of quality programs. We envision utilizing digital tools to track progress (such as clinical care or improvement cycles) and attest to meeting standards within the domains of quality verification programs. Not only could digital tools be used to attest to certain activities, but with the proper algorithms, the tools could automatically track relevant patient outcomes in real-time. This information could be displayed as a dashboard in the physicians' EHR to track quality goals, easily access relevant patient information, SDOH metrics, and ensure successful completion of care plans. In

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many ways, using these tools could eliminate excessive administrative and reporting burden by allowing physician and hospital participation in quality programs to be maintained and assessed automatically.

Use of FHIR for Current eCQMs

Area #1: Leveraging and advancing standards for digital data and obtaining all EHR data required for quality measures via provider FHIR-based APIs

To achieve this transition, CMS is considering targeting the data required for their quality measures that utilize EHR data to be data retrieved via FHIR-based application programming interfaces (APIs) based on standardized, interoperable data. CMS states that the data used for measurement could also expand beyond data captured in traditional clinical settings, administrative claims data, and EHRs.

The ACS agrees that CMS should not limit the data capture for dQMs to EHRs, or other traditional clinical settings. Today, there are many opportunities to leverage other data sources, such as risk-adjusted clinical registry data, patient-generated health data (PGHD), HIEs, and digital platforms hosted by specialty societies. ACS has developed a means for structured data capture (SDC) of key operative reports in a digital platform and is making these available for import and exchange using open standards, such as FHIR. SDC is also used and sanctioned by federal agencies in cancer pathology reports. These provide reliable and valid means for staging cancer, which is an essential step in determining treatment options and tracking survival and long-term outcomes. Optimizing data from all relevant sources will allow for a more comprehensive view of the patient through all phases of care. As CMS begins to transition to dQMs and consider data sources outside the EHR, it is important for CMS and Office of the National Coordinator for Health IT (ONC) to continue to acknowledge and address the potential challenges that may arise as digital health platforms and applications are developed. **In many cases, it can be extremely costly and unsustainable for hospitals and clinicians to establish agreements with EHR vendors that enables bidirectional exchange or access to their proprietary platforms. Therefore, CMS and ONC should work to create pathways for bidirectional data exchange with EHRs and other data sources.**

We appreciate that CMS has taken these steps to move towards promoting a broader use of the FHIR standards, but **we also recommend that CMS additionally consider ways to exchange data with digital health tools that are not just limited to FHIR-based standards. There are many other sources of patient data in standardized formats aside from FHIR that**

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would be useful to quality measurement, such as Operative Reports using SDC, clinical protocols, enhanced recovery after surgery (ERAS), and clinical CDS tools.

Area #2: Redesigning Quality Measures to be Self-Contained Tools

In this RFI, CMS discusses potential approaches for including quality measures that use standardized data and interoperability requirements that have expanded flexibility and functionality beyond CMS' current electronic clinical quality measures (eCQMs). The Agency is considering defining and developing dQM software as end-to-end measure calculation solutions that retrieve data from primarily FHIR-based resources maintained by providers, payors, CMS, and others that can calculate measure scores, and produce reports. The ACS believes that this is an extremely important step in redesigning digital quality measures and supporting the data flows needed for running a comprehensive quality program. **Transitioning to self-contained tools that can track patients across the care continuum by gathering and analyzing data for quality metrics and patient reported outcomes (PROs), as well as assessing conformance with the care plan will be highly valuable in driving improvements in care.**

Area #3: Building a Pathway to Data Aggregation in Support of Quality Measurement

CMS is considering expanding and establishing policies and processes for data aggregation and measure calculation by third-party aggregators that include, but are not limited to, HIEs and clinical registries. CMS also states that they are considering similar policies for third-party aggregators. **The ACS suggests that CMS also consider clinical association platforms, patient ID hubs within the HIE, and other similar patient-centered platforms as other sources of data aggregation for quality measurement.** We also have the technology to support tracking patients within appropriate firewalls to protect their identity while also leveraging knowledge and outcomes experience across the entire cohort. These platforms are being developed by specialty societies to offer clinicians personal analytics with systems rooted in Health Insurance Portability and Accountability Act (HIPAA) to better inform patients, payors, the care team, etc. Platforms such as this can use secure APIs to bidirectionally exchange data with HIEs, taking advantage of the longitudinal data captured in the HIE. The data are then sent to a data lake where the data are aggregated and can be shared back to the platform where physicians can view the analyzed data in a dashboard.

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The ACS urges CMS to recognize the need for a knowledge management strategy that is all-encompassing and not piecemeal. It would be burdensome if each delivery site had to meet differing requirements to interface with each data aggregator to suit the emerging needs of data in knowledge management. These needs involve care process management, case management across the care continuum, outcomes assessment, safety, conformance with guidelines, and so forth. Any quality measure aggregation initiated by a payor should have the ability to reduce data management burdens clinically and administratively.

Area #4: Potential Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

The Agency is considering the future potential development and multi-staged implementation of a common portfolio of dQMs across its regulated programs, agencies, and private payors. This common portfolio would require alignment of:

- measure concepts and specifications including narrative statements, measure logic, and value sets; and
- the individual data elements used to build these measure specifications and calculate the measure logic.

The ACS has been a strong advocate for alignment across CMS quality programs. If CMS moves forward with this concept, CMS should not only align the current CMS quality measures across their programs, but also develop new measures that are aligned across a condition or the patient's total episode of care for purposes of quality improvement including key process, structure, and outcome measures as part of a comprehensive quality program. These types of measures can then be used as actionable feedback for care teams in addition to meeting reporting requirements for federal programs.

The ACS takes measure of CMS payment incentive programs by assessing how useful the information that emerges would be for patients and for their clinical teams. Do the CMS measures bring the various teams and elements of care together to inform care and drive teams to deliver care more optimally? The ACS wonders how CMS measures success of their program. Does CMS measure success based on the level of participation in measurement, the number of participants who received payment awards? We also ask how CMS evaluates the patient's use of Care Compare website and the value of the information they offer? **It would be helpful for CMS to provide more clarity on how they assess the successes and failures of their payment incentive programs.**

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CLOSING THE HEALTH EQUITY GAP IN CMS CLINCIAN QUALITY PROGRAMS – RFI

Low patient socioeconomic status (SES) has demonstrated adverse impacts on surgical outcomes. Limits on resources, lack of preventive care, poor early detection, and limited chronic care maintenance are some of the factors that contribute to inequities. Part of CMS' strategy to address health inequities is to improve data collection and consider ways to measure and report on equity in the CMS programs to better identify and understand health disparities, develop and disseminate solutions to achieve health equity, and implement sustainable actions to achieve health equity. The ACS commends CMS on the issues and questions raised in this RFI and is committed to closing the health equity gap. As the American College of Surgeons, we witness the many dimensions of inequities in surgical care and seek to use all our resources to help the nation overcome the barriers of inequities.

When considering the recent history of the US healthcare system prior to specialty medicine, we were a nation of home cures, local 'docs,' and simple remedies. With the advancements of science came specialty medicine. It brought acute care advancements that reversed serious acute illnesses such as cancer, heart disease, renal failure, and so forth. We now live in a world of specialty medicine for acute diseases and preventive/maintenance therapies for chronic care. Care has grown in complexity and price but lacks meaningful, relevant, and understandable data available to patients to access care and navigate the system. In specialty medicine, we see more advanced disease and higher rates of complications in racial and ethnic minorities, indicating that certain patient groups lack access to preventive care and timely access to surgical care. The root cause of inequities in care is not solved by clinician metrics. It is a much larger social issue.

These advancements in healthcare have also highlighted the lack of resources allotted for safety net hospital systems who care for some of our most underserved communities. When the safety net hospital system was developed decades ago during the period when care was simpler, capitalizing a health care system to meet minimum standards was somewhat attainable. Today, in many cases, safety net systems operate with limited resources and clinicians often are forced to practice "make-do-with-what-you-have" medicine. They experience limitations in infrastructure and budgets that are needed to manage the costs of depreciation, new technology, and so forth, sometimes resulting in understaffing. All these factors can have an impact on patient access to care, oftentimes forcing patients to wait months for screening and prevention or advanced imaging and other essential healthcare services.

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In this RFI, CMS discusses initiatives to bridge the health equity gap in the MIPS track of the QPP.

Improvement Activities

CMS proposes to modify five existing improvement activities (IAs) to shift the focus toward health equity, as well as propose a new improvement activity titled "Create and Implement and Anti-racism Plan," which focuses on systemic racism as a root cause for differences in health outcomes between socially defined racial groups. CMS explains that the plan should include a clinic-wide review of existing tools and policies—such as value statements or clinical practice guidelines—to ensure that they include and are aligned with a commitment to anti-racism. The plan should also identify ways in which issues and gaps identified in the review can be addressed and should include target goals and milestones for addressing prioritized issues and gaps, which may also include development of an organization's plan to prevent and address racism, improve language access, etc.

The ACS is committed to dismantling systemic racism in surgical care. However, before encouraging individual clinicians and groups to create and implement an anti-racism plan, we support a more strategic approach. The first step might be to understand local economic and racial disparities and create a strategic plan to address health equity. One example of strategic work being done on the systems level is the Health Anchor Network (HAN), a noteworthy initiative which addresses economic and racial inequities through the influence health systems can have on a community. This work includes large and strategic investments in the hospital's local community, using a health system's economic power to inclusively and sustainably benefit the local community they serve—including hiring, purchasing, and investing locally. The Health Anchor Network aims to "define the healthcare leadership standard and promote industry collaboration for proactively addressing economic and racial inequities in community conditions that create poor health."[18] Many large healthcare systems including Kaiser, Rush, and Henry Ford, to name a few, are leading these efforts.

A more general concern that we have with the proposed IA is that the implementation of a system-wide plan (which calls for the development of a value statement, review of policies, improved language access and so on) likely has a greater chance of success if done by department heads or the facility administration, not a single clinician or a group of clinicians. **This an example of how MIPS and MIPS Value Pathways (MVPs) fail to recognize the**

[18] Healthcare Anchor Network. *About the Health Anchor Network.* Retrieved from: https://healthcareanchor.network/about-the-healthcare-anchor-network/

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critical importance of how modern surgical care is delivered, including the critical role the facility plays. How would the Agency envision this IA being implemented by surgeons? Instead, **the facility should provide the appropriate resources, infrastructure, and educational opportunities needed to create and implement any type of organizational plan. This could be part of the hospital incentive programs where the hospital attests to having and implementing an organizational plan and the individual clinician or group reports participating in the plan.**

Complex Patient Bonus

CMS proposes to update the complex patient bonus formula in MIPS to make the complex patient bonus more targeted for clinicians caring for high risk and complex patients by giving additional points to clinicians with a higher share of medically and socially complex patients. CMS notes that it intended for this bonus is to serve as a short-term strategy to address the impact patient complexity may have on MIPS scoring while it continues to work with stakeholders on methods to account for patient risk factors.

While we consider the MIPS complex patient bonus more closely targeting physicians who care for the most complex patients a worthy effort, we have two major concerns with both the clinical risk and social risk indicators. First, using the HCC on CMS administrative claims data alone are insufficient. Clinical data are much more reliable for determining comorbidities and should be used alongside administrative claims data. Second, using dual-eligibility as the sole indicator of social risk does not capture the full scope of patients who might have risk factors that contribute to the complexity of care they need, possibly reducing access for those who do not fit that definition. Only approximately 20 percent of the Medicare population falls within the dual-eligible designation, but we can assume that there are many more patients that have significant condition-specific or social risk factors that contribute to their need for more complex care even though they are do not meet the dual-eligible definition. Again, by using the dual eligible designation as the only social indicator, we are concerned access to care may be impacted for those who do not fit that definition. **Identifying patients who will require complex care is a complicated task, therefore the ACS asks that CMS continue to work with stakeholders to design a more inclusive and accurate method to identify patients and provide rewards to clinicians who treat complex patients. We also ask CMS to consider more reliable ways to further reward teams who can demonstrate improvements in care while also serving complex patients, beyond the simple tool of bonus points.**

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CMS also solicits comments specifically on the stratification of quality measure results by race and ethnicity and improving demographic data collection. In our responses to the questions posed in the RFI, we share some findings in surgery and provide insights for how we can begin to close the health equity gap.

1) **Future potential stratification of quality measure results by race and ethnicity**

Findings in ACS NSQIP

To address disparate outcomes across patient groups, the College analyzed risk-adjusted National Surgical Quality Improvement Program NSQIP data to identify and understand disparities in surgery. In our analysis of risk-adjusted NSQIP data, which includes patient data starting with inpatient admission to 30 days post-discharge, the ACS found that surgical outcomes risk-adjusted for comorbidities did not show statistical differences across race.[19] These findings have led to more research questions, including the need to analyze unadjusted inpatient NSQIP data—will the raw, unadjusted NSQIP data show a preponderance of uncontrolled chronic conditions when stratified by race and ethnicity? Are cancers detected at a later stage in certain groups? In other words, we must shine a light on the problem and avoid risk-adjusting away the differences for purposes of quality improvement and improving health equity. It is important to highlight the chronic conditions of patients who require acute care and the impact those conditions have on outcomes. An uncontrolled diabetic or hypertensive patient will fare worse if they need acute surgical services. We believe this approach aligns with the CMS intent for dealing with complex patients.

Additionally, when we consider the healthcare journey of patients in a safety net system, many of these aspects to support population health are simply not present or inadequately resourced. Safety net care is stretched beyond its limits in acute care. When measured on raw scores for event rates such as Surgical Site Infection (SSI), without risk adjustment, the incidence may appear excessive in this population. These are multifactorial problems that require more research and analysis to better define the problem. We can better serve all patients if we think of doing well across the care continuum—in acute specialty medicine, in chronic prevention, and maintenance of medical conditions. To dramatically improve the care of the safety net population, both acute and primary care must improve care coordination between each other to

19 This work has not been published in peer-reviewed literature.

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support the much-needed integration of care in this diverse population. We welcome further dialogue with CMS on our findings in NSQIP. **The ACS stands ready to help in the development of standards for aggregation and to work toward the inclusion of SDOH as part of the surgical team's dashboard.**

Expanding Current CMS Stratification Efforts

Currently, CMS is considering expanding the disparity methods to include stratification of the condition/procedure-specific readmissions measures by race and ethnicity. CMS notes the many limitations of stratifying for race and ethnicity because the Agency does not consistently collect self-reported race and ethnicity information for Medicare programs (the gold standard). Instead, CMS utilizes data from the Social Security Administration (SSA) which is less accurate. As part of this work, the Agency is working on efforts to develop consistent data on SDOH. For example, CMS has developed an Inventory of Resources for Standardized Demographic and Language Data Collection and supported the collection of ICD-10 codes for socioeconomic, cultural, and environmental determinants of health. CMS has also supported initiatives to statistically estimate race and ethnicity. ONC has included social, psychological, and behavioral standards in 2015 certified electronic health record technology (CEHRT) (however, this functionality is not included as part of the certified EHR technology required by the Promoting Interoperability performance category). The new release of USCDI v2 includes gender information, social determinants, and sexual orientation.

Because efforts to collect these data are a significant undertaking, CMS believes there is a need to better identify race and ethnicity in the short-term. As a short-term solution, CMS seeks feedback on the application of an algorithm to indirectly estimate race and ethnicity of Medicare Beneficiaries using a combination of other data sources that are predictive or race and ethnicity to permit stratification of measures in the aggregate (hospital or health plan-level), until more accurate forms of self-identified demographic information are available. CMS notes that despite the high degree of statistical accuracy of the indirect estimation algorithms under consideration, there is a small risk of unintentionally introducing measurement bias.

The ACS commends CMS for the resources it has invested in identifying ways to promote health equity and agrees that identifying means to improve the health care of certain populations who have been historically underserved should be a top priority of the agency and the entire US health care system. When we start to think about how to collect and analyze data to determine differences in health outcomes based on race, ethnicity, and

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the role of SDOH, it very quickly becomes a complex and even seemingly endless task. Currently, there is so much noise in the data that we are guessing at the cause; it is hard to know where we should focus. Even if we had well validated data, understanding these relationships would be difficult, but in this case, it is even more complex due to the lack of SDOH data, reliable race and ethnicity data, and the many methodologies available to manipulate the data. We must be more thoughtful in definitions, data needed, and appropriate methodologies. **Therefore, before CMS starts to pick measures and attempts to stratify for race and ethnicity, it is paramount for the Agency to first state the goals that it wishes to accomplish. What will be the hypothesis, scope, and analysis of this work?** Safety net and community hospitals will usually look worse compared to most private hospitals which typically see less complex patients. Is the goal to level the playing field for purposes of accountability? Or is the goal to shine the light on the disparities and to give additional resources to hospitals with sicker and more complex patients?

The current payment system also adds complexity to the scope of this work—clinically dual eligible patients are complex, and from the CMS payment perspective, they are not limited to one payment program (some are FFS, some are managed care, etc.), making it harder to track and provide the necessary support and resources. Before diving into this work, CMS must state their goals and the potential limitations so the public can understand where this work may fall short, including what information the intended goal will and will not provide. Equally important is that CMS be as transparent as possible in this work.

2) **Improving demographic data collection**

CMS seeks comments on current data collection practices by hospitals to capture demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity, language preference, tribal membership, and disability status). CMS also seek comments on other efforts we can take within the MIPS program to further bridge the equity gap.

The ACS recommends that CMS consider exploring lessons-learned from Veterans Affairs (VA) data collection efforts regarding access to timely care. The VA tracks wait times for appointment types for a new patient or established patient for various types of specialists and primary care physicians. What additional metrics does the VA track for access? What is the wait time for a colonoscopy? Or a CT or MRI? Wait time for a surgical consult for chronic pain from a hernia or chronic cholecystitis? What about wait time for emergency department admission to a floor bed? These might be important

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data to analyze to help inform CMS data collection efforts and where further research is needed.

Right now, this RFI leaves us with more questions than answers. **Measures to improve health equity for Medicare beneficiaries, including dual eligibles, should focus on how to better define the multifactorial challenges across this diverse patient population. Therefore, we strongly recommend CMS provide a strategic plan that includes a detailed and transparent goal stated for this work, a timeline, and the necessary resources and research needed to achieve the goal, including the collection of self-identified demographic information to identify health disparities more accurately across all patient groups. An extensive deep dive into addressing health equity is required in order to prioritize next steps.**

The Intersect of Data, Digital Tools, SDOH Factors, and Surgical Care

As discussed earlier, there is clear connection between SDOH factors and surgical outcomes. The ability to collect accurate and real-time SDOH data could drastically change care delivery across the phases of care, from preoperative planning to postoperative management. We envision many instances where these data can be used to provide more personalized healthcare services for patients. For example, when a patient is admitted for a surgical procedure, having up to date information about the patient's chronic care management plans and patient generated data that show their average activity levels, heart rate, insulin tracking, etc. could greatly impact the way a surgeon decides how they educate and prepare the patients in the preoperative phase of care. The surgeon might also have access to self-reported information about social risk factors from patient surveys that could assist surgeons in developing more personalized postoperative recovery and follow up plans to ensure optimal recovery.

If the collection of these data were more commonplace, we envision integrating it into clinical workflows through CDS modules available through the physicians EHR and other platforms. Throughout the phases of care, the CDS tools could apply algorithms that evaluate the patient's EHI, including other risk variables, to trigger follow-up reminders and alerts for certain medications or interventions specific to the patient's needs.

To achieve more widespread collection, aggregation, and tracking of SDOH data, improvements in collection methodologies and standardization are necessary across the entire healthcare system. In many instances these data are not widely collected and, when they are, there is variation in how it is identified, classified, and what fields are used in EHRs and other systems.

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While some systems have taken steps to develop and implement internal processes to administer surveys and gather self-reported data from patients, these practices are not widely adopted and there is still much to be done to address the gaps. **The ACS believes that developing standardized data definitions for race, ethnicity, and SDOH is a foundational barrier that, if addressed, would allow stakeholders to gather more complete data sets that can be leveraged for research, quality measurement, and much more.**

Combatting Bias Resulting from Use of Digital Health Tools

It is critical to consider bias when designing, training, and using digital health tools. Various forms of bias based on race, ethnicity, gender, sexual orientation, socioeconomic status, and more can be perpetuated through the use of certain advanced digital health tools, especially those using AI/ML. Bias can manifest in digital tools in various ways. For instance, if an AI algorithm is trained with data that fails to include all patient populations for which the tool is used, this would introduce inherent bias. Bias could also be unintentionally written into algorithms, leading to outputs that could have a biased impact on certain populations. The context in which the tool is used should also be considered when trying to avoid bias. If the tool were trained on a certain population for a specific purpose and is applied in a different setting with a different patient population with varying risk factors, this could also result in bias.

While we will be unable to eliminate bias completely, steps can be taken to validate the quality of the data and reduce bias in AI/ML algorithms. **Building a framework through collaboration with stakeholders possessing clinical and technical expertise that guides the development and validation of algorithms can assist in reducing bias if done with a high level of rigor.** The framework could include a checklist with certain steps that developers would have to complete to ensure algorithms have gone through rigorous testing and validation. By following the processes and validation criteria set forth by the framework, developers can ensure that the algorithms are free of significant bias and will output accurate predictions. This type of framework coupled with external validation that utilizes data across various practice settings and demographics, can also be applied periodically following the implementation of the tool, to ensure that as the algorithms take in real-time data, they are still achieving a high-level of accuracy.

In addition to building a framework to validate these algorithms, efforts to expand the data infrastructure to capture validated clinical data—as well as racial, ethnic, and SDOH variables—will support the development of accurate predictive algorithms. **Instead of building databases in silos where some**

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focus on capturing clinical and outcomes data and others capture public health and disparities variables, creating a master database that can integrate all these elements will be beneficial in developing digital tools and using data to better understand variation in outcomes across populations. These databases could integrate data from trusted sources such as patient surveys collected during visits and secure apps on personal devices. Using more expansive data sets will help reduce the gaps in data that are used to develop predictive models, therefore allowing the models to "learn" how to aggregate greater variations in data elements.

We also strongly recommend that in future RFIs on this topic, CMS solicit information on the necessary efforts from hospitals and clinicians to implement a coordinated strategic plan to address health equity such as: the development of standards, data collection methods, ways to address the digital divide, staff training to ensure that patients are comfortable answering all demographic questions, education on what do with the stratified data to inform quality improvement cycles, and more.

TRANSFORMING MIPS: MIPS VALUE PATHWAYS

In previous rulemaking, CMS finalized the implementation of a new participation pathway: the MIPS Value Pathways. CMS believes that MVPs will improve value, reduce burden, inform patient choice in selecting clinicians, and reduce barriers to facilitate the transition to Alternative Payment Models (APMs). MVPs aim to provide a cohesive participation experience for physicians by standardizing performance measurement around a specialty, medical condition, or public health priority and creating alignment across performance categories to decrease the siloed nature of the traditional MIPS program. In this rule, CMS proposes to incrementally implement MVPs, beginning with the CY 2023 MIPS performance year with an initial group of seven MVPs. The ACS' comments to the MVP principles and CMS' implementation plans are provided below.

As the QPP and other Medicare programs transition toward Value-Based Health Care (VBHC), the ACS believes it is important to define value based on what matters to the patient. Patient-centered value is about the judgment applied by a patient and their family for care that meets their goals at an affordable price. A patient's interpretation about their care is relative to their personal values for quality, safety, access, inclusiveness, price, trustworthiness, appropriateness and so forth. Transparently reporting on how a patient values care for a specific condition would then become a useful tool for other patients who are seeking a reasonable place for their care. The ACS believes the intent of the law is more than to purchase care based on value. We believe it is to

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inform patients about the value of the care they receive, and that this will serve as a means for driving quality improvement.

While the MVP pathway aims to move the needle on more meaningful value-based care, it is only the first step, and it must not be the last. The path forward must move to more patient centric, condition-centric value assessments that cross over payment systems and link the elements of the care team together in a coordinated manner. To do this, the next step will be the transition toward modern quality improvement followed by the transition towards team-based, value-based reimbursement models with shared accountability and ultimately bundled care for conditions, or Episodes of Care (EOC). EOCs are patient-centric and aligned with value-based payment models including alignment with the hospital, ASCs, SNF care, home health and so on from preoperative to postoperative care to include the full episode. EOCs represent a move that unites the elements of FFS payment into team-based fiscal alignment. It is also possible to use EOCs inside other payment models such as large risk-bearing entities, including accountable care organizations (ACOs), which may rely on population-based payments per member per month (PMPM). **To best facilitate this first step in transition, we urge CMS to begin implementing MVPs focused on defining value based on what matters to the patient. To start, CMS should identify what information is critical for a patient when looking for a clinician who best fits their needs for their medical condition(s).**

To the ACS, it seems that CMS assesses the effectiveness of their quality payment programs based on the types of measures used, the burden of measurement, and the level of participation in a payment program. These seem to be secondary aspects of a quality program. **The ACS wonders if a patient-centric measure of effectiveness would serve our quality initiatives. One way to do this is to consider how CMS Care Compare can provide the information that patients need to identify a clinician with the information reported through MVPs.** Is CMS' Care Compare site currently useful in guiding care for patients? Is it an instrument used to incentivize care improvement or is it just the outgrowth of an incentive payment system with extracted metrics which lack utility for the end users? Perhaps a meaningful way to highlight the value of the CMS Care Compare site is to consider the journey by creating a patient persona. How would an individual patient find the information useful?

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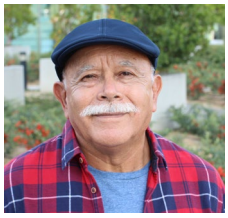
Patient Persona on Care Compare



A patient with critical aortic stenosis (AS) who lives in NY, NY, visited the CMS Care Compare hospital site and found several hospitals with high star ratings and great patient survey reports. He wondered, what do these ratings mean for patients with AS?

The Care Compare ratings gave him a general sense of hospital quality and safety by showing how some patients that were treated for unknown conditions in an unknown sample felt about their care. But the reports did little to help him in understanding the serious decisions he needed to consider for his health and his particular condition. He went back to the Care Compare site to see what he could find under the physician section. Which specialty should he explore? Cardiology? Cardiac Surgery? He picked the cardiologist since he would like to avoid an open-heart operation. His search turned up 300 cardiologists within 10 miles of his location. The report gave no specifics related to his condition. To learn more about a cardiologist, he would have to select one and 'click' on a name to get more details about this physician. He randomly selected a cardiologist for review whose office seemed to be nearby to a major medical center. The site reported this cardiologist participated in Medicare. What performance information did the compare site reveal? It reported that the cardiologist met the standards for using electronic medical record technology. He felt no more educated about where to get specialty advice about his AS after visiting the Care Compare site and was very frustrated. He still had no sense of where or how to get the assistance except to keep scrolling through 300 cardiologists hoping to find more information.

He then spoke with his PCP who referred him to someone she trusted. He wondered how she came to this judgment but had no other way to assess the care except for her advice. Perhaps he would check with others to see if 'word of mouth' referrals agreed with his PCP?

Patient-centric Measures of Effectiveness

This patient's experience shows us that building a quality program based on incentive payment program metrics makes it difficult to provide patients or care teams with meaningful information. Even worse—for clinicians looking to improve quality, Care Compare uses a different benchmark for public reports than they do for MIPS incentive payments, and now CMS is proposing to rely on a third and different indicator of quality measures under the proposed MVP enhanced feedback reports for confidential performance feedback reporting to clinicians. This is confusing to the provider in terms of understanding what

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goal post they should be aiming for. While it is reasonable that clinicians may rely on different metrics for quality improvement efforts than are posted for patient decision making, there should never be contradictory information such as two different performance rates for Surgical Site Infection (SSI), for example.

Another example for consideration is tracking something like avoidance of SSI for breast cancer (episode-specific) which might be useful for driving quality improvement (QI) efforts for a clinical team, but the patient might be more interested in metrics such as resumption of activities of daily living, meeting body image goals, or involvement in the decisions of their care.[20]

MIPS cost data reported on Care Compare are another potential source of confusion. If you consider all the various cost measures being used and the different methodologies implemented, it will be a "noisy" environment. Total cost per beneficiary is too blunt an instrument and draws little actionable attention. Acumen's methodology is a gross misrepresentation of true price and seeks to represent a narrowed view of cost by only accounting for that which is assuredly appropriate and uniquely clinician-attributable rather than what is more plausible, realistic, and patient-centric. In addition, related law now calls for hospital price transparency and advanced explanation of benefit (EOB) reporting.

The ACS believes it is essential to create consistent standards in price transparency which best reflect true patient costs. We again think it is a useful exercise to measure the effectiveness of cost measures from the perspective of the patient persona. Does the clinician under the patient's consideration participate in care models where the entire episode of care provides the affordability that patients can understand and decide to accept or reject? **Patients want to know two major factors: where to get the best care and what care will cost them.** Clinicians do not have the information to give them because MIPS quality does not align with cost and cost measures are too narrowly defined to reflect true costs to patients. **Logically for a value expression (V=Q/$), measurement of the price of care and quality should align based on a single standard so that information provided to patients to make informed decisions on their care is consistent across all aspects of care**. With all the metrics for cost and quality, what source should they trust? Is any of this information meaningful or actionable?

In summary, MIPS or MVP, it does not matter which, currently fall short of the mark for informing the AS patient or helping care teams understand price,

[20] Sage, J., Witowski, M., Opelka, F. (2021). Expressing value in health care. *Bulletin of the American College of Surgeons*. 106(7), 24-33. https://bulletin.facs.org/2021/07/expressing-value-in-health-care/.

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quality, safety, and overall outcome attainment for a specific condition or procedure. What other options does CMS have? What if the patient was able to find a CMS Care Compare site that was organized by condition, represented as episodes of care with measures that are meaningful to patients, and drive QI cycles for clinicians? It is important to focus on the presentation of data to the end users as well as the underlying metrics themselves. However, if we are not measuring the right metrics in the right way, it does not matter how we present the data. **As illustrated in the patient persona example, the ACS is concerned that unless MVPs are a step in the progression to patient level measures for a condition, MVPs seem to be more of the same set of MIPS metrics reorganized into categories. If we make the same mistakes with MVPs, we cannot expect a different outcome than we have seen with MIPS.**

Failed Hypothesis for Driving Quality Improvements

ASC believes CMS must rethink the quality measure framework. For nearly a decade, the quality measure enterprise has operated with the hypothesis that if we use performance metrics in payment incentive programs with adequate levels of participation, accountability in public reports and clinical feedback would be enough to establish a culture of quality improvement. However, this hypothesis has fallen short of the mark; it has not achieved what we have tried to achieve in driving high quality. We believe there are two primary reasons for this:

1. It is hard to develop reliable and valid quality metrics given the intricacy of care and due to the complex science of quality measurement. It has proven very difficult to make a measure generalizable on the national level that is also useable, feasible, and at the same time will move the needle in quality on a large scale.

2. For clinicians and patients, most of the MIPS metrics are not usable in terms of what happens in day-to-day delivery of care across the various care settings each patient faces when undergoing surgery, making the measures void of meaning and actionability. The result of this is that clinicians have essentially participated by choosing the path of least resistance that results in the lowest negative payment implications. As illustrated in the patient persona, this method has not resulted quality measures that are helpful to inform patients and hardly drive real improvements in care, except in very small specific areas.

Simply put, incentivizing payment using limited, unaligned performance measures is failing to achieve the intended goals. **Measures are not**

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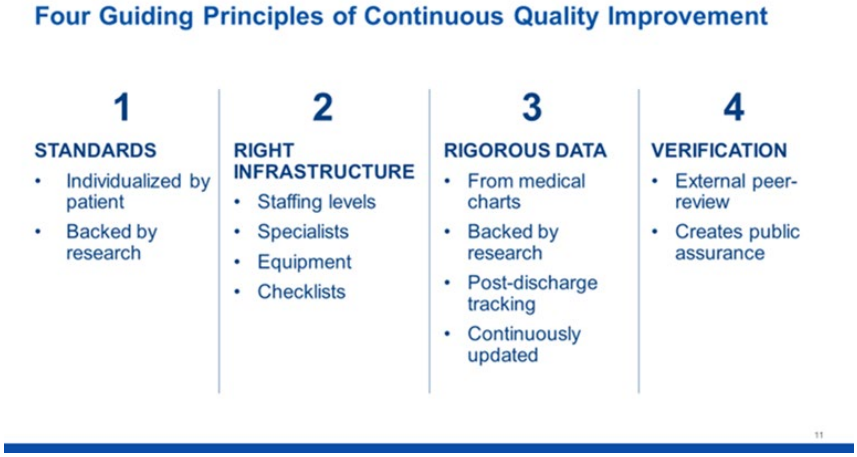
meaningful unless patients find the measures to be informative and useful for their care and that care teams respond in kind by building QI into their culture; measures should be judged based on the impact they have on QI to achieve value-based care. Additionally, when it comes to quality, payment incentives are an important lever, but not the only lever. Transparency has the effect of accountability and influences other factors such as market share. Balancing all the behavior incentives such as personal professionalism, market forces, revenues and compensation rewards are all arrows in the quiver for driving quality improvement.

We Need a New Hypothesis

The ACS sees a path forward for CMS and other payors to achieve the goals of providing patients with the necessary information about where to get care that suits their clinical needs and how to establish its affordability. For more than half a century, the ACS has viewed quality in the context of programs that are evidence-based and demonstrate improvements in care, while measurements are key components of such programs. Based this work, the ACS asserts we must consider a new hypothesis for the quality measure enterprise. **To drive real improvements in care we must appreciate and incentivize all the components of a comprehensive quality program— high value process, structure, resources, data, event rate monitoring, patient reported outcomes.**

Solution: Incentivize a Comprehensive Quality Program

The College's solution to a comprehensive quality program is based on the ACS Quality Model—it informs the patient and brings together a team to drive quality improvement with standards, as illustrated in the Four Guiding Principles of Continuous Quality Improvement:



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The ACS Quality Model has a history of aligning facility and providers for seamless, continuous reliable standardized care. The program includes such attributes as demonstrable commitment to surgical quality from the C-suite; appointment of a surgical quality officer and surgical quality committee; establishment of a hospital safety culture; a formal case review process; standard surgeon onboarding, credentialing, and privileging policies; data systems organized to find problems (such as complications and inefficiencies) and fix them; and so on. There is evidence in the peer reviewed literature that patients have better outcomes if they are treated in a verified center. For example, in one study, the overall risk of death was 25 percent lower when care was provided at a trauma center than when it was provided at a non–trauma center.[21] Again, it is so much more than just holding clinicians accountable to specific quality measures.

The ACS Clinical Programs are based off the ACS Quality Model and rely on having the right structure and processes in place to achieve positive outcomes and assure safe care for surgical episodes of care. ACS Clinical Programs set the standards for clinical care and these programs are where condition- or specialty-specific (such as Bariatric, Trauma, Geriatrics) standards are added. Layering on top of clinical accreditation are appropriate and adequate processes that further help to implement the care model. Moving up in the hierarchy of the key components are monitoring of clinical outcomes with accurate, clinical, risk-adjusted data—the model used in the ACS NSQIP®—followed by outcomes reporting by the patient, or PROs. Population health measures, as a required component to MVPs, should report community-wide on how the team is doing in a domain of care—such as for cancer—looking at prevention, early detection, long term survival and so on. In other words, indicators that are domain-specific to signal to the care team how they are doing in their community. **Each component of the quality model builds on and is interrelated to the others; pulling the information to assess the essential components for a patient thereby allowing for patients, clinicians, facilities, and payors to assess more completely the quality of care.**

Based on our experience in running quality programs, we assert that the goal for MVP should be to incentivize a comprehensive quality program that provides information that patients need to make decisions about care and the information, resources, and structures clinicians need to drive quality improvement transition toward measures that meaningfully inform true quality improvement cycles.

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[21] MacKenzie, EJ., Rivara, FP., Jurkovich, GJ., et al. (2006) A national evaluation of the effect of trauma-center care on mortality. *New England Journal of Medicine*, *354*(4), 366-78. https://pubmed.ncbi.nlm.nih.gov/16436768/

MVPs should be developing a pathway to reporting information that matters to the patient seeking care based on conditions or episodes. This information should not be siloed based on individual clinicians or facilities, but instead should link clinicians and facilities to create care coordination with shared accountability:

1. **PROMs: Did patients report good/excellent outcomes for an episode of care?**
   This can be represented by episode-specific patient reported outcomes, indicating whether goals of care were met.

2. **Verification or Accreditation: Does the care team have what they need to deliver optimal care for that condition?**
   This can be represented by a verification program or similar quality program that ensures the care delivered has met structure and process standards within a clinical domain to measure outcomes, safety records and enter into improvement cycles.

3. **Event Rate Reporting: Is the care safe for that condition?**
   This can be represented by event rates for quality and safety assurance pertinent to the episode. Reporting reoperation for breast cancer which has low readmissions rates compared to patients with open heart surgery for a valve replacement should not be used as an apples-to-apples comparison across breast surgeons and cardiac surgeons.

4. **Price Data: What can the patient expect the overall cost to be for the episode?**
   The ACS applauds ongoing efforts to provide price transparency for an episode of care (EOC), but these efforts should align with episodic cost measures. It is important to establish what is meant by an episode and these definitions should be standard. Rarely does complex medical care involve a single transaction. When care is simple and limited to a transaction or two, cost is typically not a problem. More complex care involves multiple transactions over a period of time, and, to a patient, these costs can be painfully additive. By reporting on standard episodes, it is possible to avoid confusion to patients and for providers. The information becomes more actionable for everyone. In addition, price transparency is becoming part of different payment programs in commercial, federal, and by state systems. The ACS feels efforts are necessary to create consistency across all federal programs for through use of common episode structure. Other Agency efforts to provide direct contracting or price transparency are generating interests in EOCs or bundles.

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We believe that patients, as a natural extension, will want to understand the quality of care for their personal condition that aligns with the episode price. When a patient wishes to become more knowledgeable about their care, they look for episodes which appear to cover their condition and to understand the care journey as they enter into it. They look for services related to her/his condition in her/his locale. To create a website that has this information would be invaluable. For example, episodes can be categorized into large domains like cardiac, musculoskeletal, or cancer episodes. Patients would look for the cardiac episode domain and drill down to find their condition. If aortic stenosis (AS) was considered as a condition within the cardiac care domain of episodes (Clinical Affinity Groups – CAGs), a patient could appreciate institutions which reported their outcomes, volumes of patients treated with this condition, quality ratings for general cardiac episodes, and any specifics for AS if volumes were adequate and worth reporting. The patient would be able to know whether the care site met general cardiac care standards, as well as cardiac surgical care standards. Perhaps if the specific cardiac domain is not reporting highly specified standards, the delivery system may be able to reflect whether the site meets the standards for geriatric surgical care. Some institutions may be certified in both complex cardiac care and geriatric surgical care. The dates for each verification review attestation to how current the sites were in meeting the standards, within 1 to 3 years, could be available. The cardiac standards would also specify services, their quality and safety record for those services, volumes and patient reported outcomes. Price transparency would provide general overall costs for the average or typical service.

In conclusion, the ACS approach is to move to Episode of Care built on a value expression (V=Q/$) and placed in contractual arrangements for a team-based, risk bearing entity that relies on value-based revenue. The value-based incentive payment could be based on elements a payor would extract from the ACS quality model (verification, event rates, and PROs) and implement in scoring for their payment incentive programs. In this model, the team members in a risk-bearing entity would have shared accountability, working together to deliver care as optimally as possible. In addition, this episode approach would be consistent with the price transparency law for the episode.

MVP Transition

CMS requests comment on innovative ideas to help achieve desired MVP results of improving value, reducing burden, helping patients compare clinician performance to inform patient choice in selecting clinicians, and reducing barriers to movement into APMs. CMS notes that the Agency is interested in targeting a focused episode of care as well as MVPs that measure the patient

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journey and care experience. CMS is also interested in how MVPs could measure the value of multi-disciplinary team-based care.

As discussed above, the ACS asserts that it is critical to keep in focus that MVPs are a means to an end and not an end in itself; the MVP "pathway" is the first step toward value-based care**.** As CMS transitions to MVPs, the Agency must consider how the program can drive real quality improvement which will require QI to be the focus for quality. In our experience running quality programs, it has become clear that no matter how "good" someone considers quality measures, the key is using the measures to improve.

The next step in the transition will be the move toward modern quality improvement followed by the shift towards team-based value-based reimbursement models with shared accountability and ultimately bundled care for conditions, or Episodes of Care (EOC). EOCs are patient-centric, aligned with value-based payment models and include all aspects of care from preop to postop. **Quality should set up quality improvement, and quality improvement efforts should reflect new efforts to enhance quality—a virtuous cycle. MVP IAs should be a program to educate care teams to track compliance and performance in PROs, and then demonstrating a data-driven quality improvement activity. The ACS believes CMS should define a roadmap that ultimately leads to quality that informs patients, drives surgical teams to excel, and uses business incentives from the payor to reward those who achieve and are exemplar.** We understand that when applying the principles the ACS has espoused, there may be statutory constraints that require CMS to be creative in how to combine quality and IA into some aspect of shared scoring.

MVP Implementation

The College envisions the implementation of MVPs as individuals working on a portfolio of domains (trauma, cancer, complex GI, cardiac, etc.) in the clinical area they treat, tracking event-rates relevant to the episodes within their domain, episode-specific PROs, and meeting the standards of care within that clinical domain, as described. And, as part of the measures included in an MVP, it is more helpful to have measures that target the episode, not system measures (such as readmissions), to help patients understand and choose care as it relates to their condition. **We also recommend that CMS develop a prioritized list of episodes to build since it is not possible to build out every possible episode. In developing criteria, CMS must remain focused on the patient using CMS Care Compare when seeking information for their condition.** Implementation across many specialties will require more creative

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management from CMS. The goal must remain centered on the highest rewards for actions that best inform patients and drive care teams to improve.

CMS' goal should be to reach a point in their quality programs where they are trusted enough that a member of Congress could visit their Care Compare website and find what they need to inform their family members where to optimally find stroke care, cancer care, trauma services, total joint replacement, etc. Those results would establish the team member options, their overall quality relative to the patient's condition, the volume of services compared to the region, and the expected total episode price along with regional and national estimates for comparison.

MVP and Subgroup Implementation Timeline

CMS proposes to delay the implementation and availability of the proposed MVPs, until the 2023 performance period/2025 MIPS payment year. CMS also proposes voluntary reporting of MVPs to prepare stakeholders through the transition plan for MIPS before potentially retiring traditional MIPS and requiring all MIPS eligible clinicians (ECs) to participate through an MVP (or the APM Performance Pathway (APP)).

The College agrees that a delay in the implementation of the proposed MVPs is appropriate given the clear need for more strategic planning to avoid a repeat of the failures in the MIPS program. We encourage CMS to develop a transparent process to engage stakeholders to help innovate MVPs for patient-centric value and help decide what MVPs to prioritize from the patient perspective. Additional time will also be needed to consider alignment of measures across CMS programs, including MVP/MIPS measures and CMS facility measures.

Transparency is critical during this process to ensure that the MVPs are appropriate and meaningful to all members of the healthcare team for the condition or episode. CMS should establish a formal process to ensure transparency and early involvement of all relevant specialty societies in the development of MVPs. CMS should also adopt a formal criterion to ensure that MVP development is clinician-led. Furthermore, CMS should provide clear and timely feedback about why a candidate MVP submission might not have been proposed for implementation.

Lastly, a delay will give practices time to reorganize how the care teams report MVPs within their TIN. For example, institutions who have traditionally reported through the CMS Web Interface will need to consider reporting via sub-groups which will require administrative reorganization, possible changes

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to the practice's business model, as well as investment in new technology to capture the appropriate data across the care team. If MVPs are truly a move toward value-based care, practices may also change workflows for more integrated patient and formal processes for quality improvement. **To this end, the ACS supports voluntary participation in MVPs for the foreseeable future, and at least until there is a well-established inventory of MVPs for clinicians to report.**

Subgroup Composition

To align with the MVP guiding principles finalized in the CY 2021 PFS final rule, CMS proposes to establish subgroup reporting as an option for MVP Participants and those individuals and entities who choose to report the APP. Within this section, CMS proposes: (1) definition of subgroup reporting, single specialty group, multispecialty group, and special status designation; (2) subgroup eligibility requirements; and (3) application of the low-volume threshold and special status designations for subgroups.

CMS proposes to define a subgroup as "a subset of a group which contains at least one MIPS EC and is identified by a combination of the group TIN, the subgroup identifier, and each MIPS EC's NPI." The group would be responsible for identifying their affiliated subgroups, and the subgroups would submit data on the MVPs that are relevant to the MIPS ECs within the subgroup. CMS also proposes that clinicians in the subgroup would receive their final score based on the subgroup's combined performance. CMS considered other limitations for subgroup composition but is not proposing any additional criteria at this time.

Critical to the transition toward Episodes of Care (EOC) is the incentive for care teams to organize around a patient to treat their condition with shared accountability. Therefore, it is important that CMS ensure the MVP implementation of subgroups does not unintentionally isolate specialties or discourage coordinated and team-based approaches to care across clinician types. **We seek clarity on how CMS will prevent this given how CMS plans to benchmark performance. As described in detail in the MIPS Transformation section, the ACS believes the path to team-based integrated care is organized around the patient (not the services in a payment system) by determining what matters to the patient alongside what the clinical team must track to deliver on patient goals and ensure patient safety.** This requires episode-specific patient-reported outcomes, indicating whether goals of care were met, tracking event rates pertinent to the episode to ensure patient safety, and ensuring that the team has want they need to deliver optimal care for an outcome which can be achieved through

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verification of care for the condition that ensures the care delivered has met structure and process standards within a clinical domain.

To achieve patient-centric value, individual clinicians participate in the care for a patient in the context of an episode. For example, a surgical patient may receive care from a PCP, surgeon, anesthesiologist, medical specialist, radiologist, and a pathologist. These clinicians have their distinct roles in the context of team-based care, and together share accountability for the cost and quality of that episode for that patient. **To this end, we encourage MVP subgroups to be organized similar to Clinical Affinity Groups (CAG), which are sets of clinicians who regularly participate together in episodes of a given type, medical or surgical, and thus form the normative standards of care for those episodes.** CAGs are designed to make sense to clinicians by providing specific and meaningful clinical contexts (episodes) that are needed to make inferences about quality and cost. Most, if not all, team members for any individual episode of care would be members of a particular CAG (or subgroup), though not all CAG members would be on the team for a specific episode. Individual clinicians should work on a portfolio of domains in the clinical area they treat.

MVP Requirements

MVP Development Criteria and Maintenance

Within the rule, CMS addresses multiple topics and puts forth the following proposals that focus on the development of MVPs.

Requirement of Outcomes or High Priority Measures

To align with the proposal in this rule to require MVP Participants to report one outcome measure or high priority measure (if an outcome measure is not available), CMS proposes that beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, MVPs must include at least one outcome measure that is relevant to the MVP topic so that MVP Participants are measured on outcomes that are meaningful to the care they provide. In addition, beginning with the CY 2022 MIPS performance period, each MVP that is applicable to more than one clinician specialty should include at least one outcome measure that is relevant to each clinician specialty included. CMS also proposes to allow the inclusion of outcomes-based administrative claims measures within the quality component of an MVP.

Beginning with the CY 2022 MIPS performance period when outcome measures are not available, each MVP must include at least one high priority

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measure that is relevant to the MVP topic. In addition, beginning with the CY 2022 MIPS performance period/2024 MIPS payment year, each MVP must include at least one high priority measure that is relevant to each clinician specialty included. CMS defines high priority measures to include outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measures.

As stated throughout our comments, the ACS views quality as a program that incorporates interrelated structure, processes and key outcomes that drive quality improvement cycles. A critical element in developing a quality program that drives improvements in care is ensuring that the proper metrics are selected. These metrics should be consistent with the care processes and support the goals for care determined by the patient and their physician. **In a quality improvement cycle, the metrics used should give physicians information that they can use to directly inform improvements in care processes, and if this connection cannot be made, then the "right" metrics are not being gathered.**

While we acknowledge the importance of gathering outcomes data, without selecting the proper measures and aligning those metrics with the other elements of a quality program, the data is informational, rather than actionable. Therefore, **we ask that CMS reconsider how they are implementing MVPs, and more specifically selecting the measures they are using to evaluate physicians' performance. The measures CMS has selected and are requiring within MVPs may allow for the administration of payment incentives for individuals, but lack the ability to inform patients, create clinical alignment, and support quality improvement cycles.**

Encouragement to Include Patient-Centered Measures

CMS is not proposing any revisions to this previously finalized criterion that considers the inclusion of (to the extent feasible) patient-reported outcome measures (PROMs), patient experience measures, and/or patient satisfaction measures. However, CMS requests comment on whether there are other aspects of patient measurement that should be considered as a part of the patient-centered measures definition.

As discussed in previous sections, value in health care must focus on what matters to the patient, with the goal for all stakeholders to deliver care based on what the patient values. Therefore, **MVP measures, including those reported on CMS Care Compare, must consider a framework and a visual representation in attempt to express a patient's perspective on the value of**

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health care they receive relative to their goals and expectations. This must illustrate the multidimensional nature of value for patients by appreciating that patients individually value different elements of care.

A patient's value assessment relies heavily on PROMs appropriate for the condition. PROMs tailored to a condition or episode allow clinicians to better understand the elements of care their patients value most and empower patients to work with care teams to communicate goals and engage in shared decision making prior to and during care. Dimensions that are critical for inclusion in the "numerator" of a value relationship (V=Q/$) will vary based on the condition—for example, the numerator for colon cancer will be different from what is needed for breast cancer, a knee replacement, mental health conditions, and so on.

PROMs indicate whether the operation or intervention was successful based on why the patient sought care and whether the treatment was able to deliver results on the goals of care. PROMs may include such factors as whether the patient was able to regain function, if the treatment relieved their pain, if they were able to return to normal activities, and so on. PROMs also can be used for digital symptom monitoring, as they have been shown to be effective at improving symptom control, quality of life, survival, and less frequent emergency department visits (demonstrated in cancer patients).[22, 23]

Also critical for a patient-centric approach is to incentivize the use of episode-based PROMs in the CMS facility programs that are aligned with MVPs. One way to consider alignment of PROMs at the clinician and facility level is to measure whether the facility has the infrastructure to measure a specific PROM for a condition, and then the clinician can be measured based on a quality improvement plan to follow up on the responses to the same PROM.

Patient experience measures should reflect whether patients felt they were treated respectfully, whether they felt their voice was heard and personal goals understood, and if they experienced a trusting relationship with the care team

<u>Health Equity Measures in MVPs—RFI</u>

CMS acknowledges a lack of health equity measures, which the Agency intends to prioritize through future cycles on measure development. CMS also

[22] Basch, E., Deal, AM., Dueck, AC., et al. (2017). Overall survival results of a trial assessing patient-reported outcomes for symptom monitoring during routine cancer treatment. *JAMA*, *318*(2), 197-198.
[23] Basch, E., Deal, AM., Kris, MG., et al. (2019). Symptom monitoring with patient-reported outcomes during routine cancer treatment: A randomized controlled trial. *Journal of Clinical Oncology, 37*(6), 528.

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explains that they believe there is potential to address health equity, specifically all seven MVPs proposed in this rule, including improvement activities related to health equity. CMS solicits information on whether there should be specialty-specific health equity measures.

The ACS commends CMS for the resources it has invested in identifying ways to promote health equity. The College agrees that identifying means to improve the health care of certain populations who have been historically underserved should be a top priority of the agency and the entire US health care system. When we start to think about how to collect and analyze data to determine differences in health outcomes based on race, ethnicity, and the role of SDOH, it very quickly becomes a complex and even seemingly endless task. Currently, there is so much noise in the data that we are guessing at the cause; it is hard to know where we should focus. **Therefore,** the **ACS believes an extensive deep dive into addressing health equity is required in order to prioritize next steps across all CMS programs, including MIPS/MVPs.** To start, measures to improve health equity for Medicare beneficiaries should focus on how to better define the multifactorial challenges across the diverse Medicare patient population. **We strongly recommend CMS provide a strategic plan that includes a detailed and transparent goal stated for this work, a timeline, and the necessary resources and research needed to achieve the goal, including the collection of self-identified demographic information to identify health disparities more accurately across all patient groups. Part of this plan might include priority areas where there are demonstrated disparities in care, such as access to bariatric surgery.** [24, 25]

To begin thinking strategically about health equity measures, we recommend CMS consider the following types of measures:

Measures of Inclusivity

The ACS strongly supports the development of PROs and patient experience measures to gather feedback directly from the patient without interpretation of the patient's response by a clinician or anyone else. CMS should prioritize measures that focus on patients' feeling of inclusivity. **Inclusivity measures are a much-needed area of development in health care and could encompass a patient's experience of receiving care that is sensitive to culture, beliefs, language, race, and personal circumstances along with feelings of trust, communication, autonomy, and more**. Developing and

[24] Gould, KM., Zeymo A., Chan, KS., et al. (2019). Bariatric surgery among vulnerable populations: The effect of the Affordable Care Act's Medicaid expansion. *Surgery. 166*(5), 820-828.
[25] Hoffman AB, Myneni AA, Orom H, et al. (2020). Disparity in access to bariatric surgery among African-American men. *Surgical Endoscopy. 34*(6), 2630-2637.

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implementing patient-reported metrics of inclusion in the care process is also an important step in addressing systemic bias in health care delivery.

Measures of Access

Another area for consideration is measures that focus on access to surgical care. These types of measures can provide information on whether patients gained timely access to a surgeon when/if they needed surgery. This could be a set of measures that track whether the system was able to ensure a timely access and referral to surgical care. This can incentivize better care coordination between chronic and acute care to improve health equity. Timely and appropriate care can lead to overall better patient outcomes.

Measures of Patient Risk

We would also seek measures that assess the patient's preoperative risks and expected outcomes based on their overall preop care for chronic conditions which affect surgical outcomes (DM, COPD, CHF, and so forth). Acute surgical care in poorly managed chronically ill patients may lead to suboptimal outcomes and increase costs. Patients with unmanaged diabetes may present with HbA1c in excess of 8.0 for elective surgery. This poor glucose control makes a patient high risk. In a safety net system, it is not uncommon for preoperative diabetes referrals to primary care or medical specialties to be three to six months later. Delays in care may be intolerable for patients with severe acute conditions requiring urgent surgical care, such as cancer care. Similarly, there are often delays in preoperative advanced imaging when CT or MR scans cannot be scheduled for preoperative staging. The impact is that surgical planning differs compared to institutions that have ready access to all preoperative services typically required for care.

Establishing a Portfolio of MVPs

CMS proposes seven MVPs that will be available for voluntary reporting beginning with the CY 2023 reporting period/2025 payment period. The proposed MVPs focus on the following topics: Rheumatology, Stroke Care, Ischemic Heart Disease, Chronic Disease Management, Emergency Medicine, Lower Extremity Joint Repair, and Anesthesia. Transparency is critical to ensure that the MVPs are appropriate and meaningful to all members of the healthcare team for the condition or episode. For example, organized neurosurgery was not consulted during the development of the Stroke MVP despite the contributions of neurosurgeons to the treatment of stroke patients in the acute care setting. **CMS should establish a formal process to ensure transparency and early involvement of all relevant specialty societies in**

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the development of MVPs. The process may involve defining the care pathway for a patient with episodes of care that are contained within the seven clinical affinity groups defined by CMS. It may also mean understanding the roles and contributions of the appropriate clinical experts for the episodes. For example, osteoarthritis and joint replacement episodes involve PCPs, rheumatologists, orthopedic surgeons, radiologists, and physical therapy/rehabilitation medicine. Additionally, **CMS should adopt a formal criterion to ensure that MVP development is clinician-led and incorporates inputs from other appropriate stakeholders.** Lastly, CMS should provide clear and timely feedback about why a candidate MVP submission might not have been proposed for implementation.

The ACS also recommends that CMS develop a transparent process to prioritize what MVP episodes need to be built since it is not possible to build out all episodes. In developing criterion, CMS must remain focused on the patient in Care Compare seeking information for their condition to help facilitate value assessment.

Proposed MVP Reporting Requirements

Each proposed MVP includes an inventory of quality measures, improvement activities, cost measures, and population health measures that CMS believes are relevant to the MVP's specific focus area. MVP participants have less reporting requirements than clinicians reporting in traditional MIPS, which aligns with CMS' efforts to implement MVPs as a pathway to reduce reporting burden. As such, MVP participants are required to select and report on four quality measures, including one outcome measure (or a high-priority measure if an outcome measure is not available). To meet the reporting requirements for IA in a MVP, participants must report one of the following: two medium-weighted activities one high-weighted activity; or participate in a certified or recognized patient-centered medical home or comparable specialty practice.

Proposed Improvement Activity Requirements in MVPs

CMS proposes that MVP Participants who report an MVP, must report one of the following: two medium-weighted improvement activities; one high-weighted improvement activity; or participation in a certified or recognized patient-centered medical home (PCMH) or comparable specialty practice.

The ACS believes that the quality and improvement elements of an MVP should be interrelated, instead of two disconnected categories. Quality measures should be developed to support improvement efforts, but in many cases, we have lost focus of this and use measures as separate standalone

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metrics. From the ACS perspective, quality metrics are a foundational element of a quality improvement program, but the goal is to gather data through the quality measures to drive improvements in patient care. Improvement activities should simultaneously and seamlessly embody the improvement cycle that is driven by quality measures. If quality data is provided to physicians or groups but they are unable to facilitate improvements in care based on those metrics, then the measures are not effective. **Therefore, the ACS continues to advocate for cohesion between quality measurement and improvement cycles. We believe that driving true improvements in care requires the successful implementation of all elements of a quality program—including structure, process, and outcomes—that ultimately inform improvement. We have heard from many program participants who met the quality program standards and had access to high fidelity risk adjusted clinical data that they did not know what to do with the data to improve.** In response to this feedback, the ACS developed the Surgical Quality Improvement Course an introductory (basic) course on quality improvement. The course focuses on practitioners performing or overseeing improvement efforts including surgeons, trainees, and residency program directors, to name a few. The ACS basic course is broadly applicable to surgery and teaches key quality improvement concepts and the quality improvement process—including how to start a QI project, data measurement, and analysis. The course also offers tools for current state and root cause investigation and data analysis, change management for QI, measuring patient safety, and building a QI team and fostering a culture of quality improvement. In addition, the College will offer an advanced course, which focuses specifically on ACS Quality Programs, such as a Commission on Cancer course using the National Cancer Database (NCDB) data, for example.

Proposed Reporting Requirements for the Foundational Layer: Promoting Interoperability

In the CY 2021 PFS final rule, CMS stated that an MVP must include the full set of PI measures and that MVP participants are required to meet PI category reporting requirements that are consistent with what is established under traditional MIPS. In addition, CMS proposes to require that an MVP participant that is part of a subgroup would be scored based on their affiliated group's performance for the PI category. From the ACS' perspective, CMS' decision to maintain the same rules and measures for the PI portion of an MVP is an example of how MVPs are merely a reshuffling of the traditional MIPS categories. As we have stated in previous comments, we believe **the PI category should be restructured to enable interoperability beyond EHRs. To truly promote interoperability, CMS must incentivize the use of enhanced digital health IT capability.** Having functionalities for digitally

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enhanced data aggregation should be a minimum standard for health IT in the MVP program. EHR requirements should support meeting national standards that enable the bidirectional movement of health data across the digital environment. In this environment, APIs can flourish to deliver performance measures, inform patients, and to share knowledge with registries and other smart devices.

Quality improvement using digital services should focus on supporting a digital services landscape that goes beyond simply aggregating quality metrics. Instead, it should leverage digital services through open standards-based platforms that can enhance knowledge sharing around care and enable the following services:

1. Support the use of **clinical decision support** to make clinical guidelines and pathways available as a digital service through platforms that are not constrained by proprietary efforts from EHRs.

2. Support the ability to **gather cohort data for outcomes** reporting, for conformance with standards-based care.
3. Support **research and clinical trials** for expanding sample sizes in randomized clinical trials (RCTs) and observational studies.
4. Support **quality metrics payors** seek for their payment incentive programs in a patient centered manner.

Proposed Reporting Requirements for the Foundational Layer: Population Health Measure

In the CY 2021 PFS final rule, CMS discusses the inclusion of population health measures calculated from administrative claims-based data as a part of the foundational layer of MVPs. CMS proposes to codify that a population health measure is a quality measure that indicates the quality of a population's or cohort's overall health and well-being, such as access to care, clinical outcomes, coordination of care and community services, health behaviors, preventive care and screening, health equity, or utilization of health services.

Instead of requiring physicians to report on generic population health measures, the ACS asserts that the measures should be focused on the domain of care that is most relevant to the care the physician provides. The measures should report community-wide on how the team is impacting the specific domain of care. For example, an MVP focused on trauma surgery should include a population health measure that focuses on what the group is doing to help reduce violent acts in their community, or an

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MVP for cancer care could look at prevention, early detection, long-term survival, etc.

Scoring MVP Performance

CMS proposes to score MVPs with the same scoring policies finalized in traditional MIPS. This means that MVP participants will be scored based on their performance on measures and activities in the four MIPS performance categories; the performance standards for each performance categories; calculation of achievement and improvement scores; and calculation of final scores.

Scoring Quality and IA

As discussed thematically throughout our comments, the transition toward value centered on the patient must shift focus from the individual accountability of traditional MIPS toward the team-based nature of care. To transition toward value, MVPs should be developing a pathway to reporting information that matters to the patient seeking care based on conditions or episodes. The ACS Quality Model leads this work and when translated to MVPs should consider how to weigh the various comments into an aligned Quality and IA score as described by general concepts in the remarks below:

- Highest Weight
  PROMs: These measures are assigned the highest value since these are most aligned with the patients' goals and expectations. For their initial implementation in an MVP, these may be general PROMs applied broadly across clinical domains. As these measures mature over time in future years, we would expect the or PROMS that may be more episode-specific when available (e.g., PROMS for joint replacement). Data for PROMs can be collected through clinical data registries or other data sources.

- Mid Weight
  Verification or Accreditation for a Condition: Patients seem to be aware when the care environment demonstrates that it is part of a well-structured clinical care programs with clearly aligned, smooth business processes. The ACS verification programs ensure the care delivered has met structure and process standards within a clinical domain and the accreditation includes that the program reviewed involves measured outcomes, safety records, and pathways to enter improvement cycles. A structural measure could be modeled after the Hospital Inpatient Quality Reporting Program (IQR) Maternal Morbidity Structural

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Measure attestation measure, in alignment with facility quality efforts.[26]

As another alternative for scoring verification measures beyond attestation, CMS could model a measure after the Bundled Payments for Care Improvement Advanced (BPCI-A) measure, Bariatric Surgery Standards for Successful Programs.[27] In this example, verification could be scored based on credit for how clinical teams meet standards:

- 0 Points: The hospital does not meet the criteria as enumerated by the specific standards.
- 1 Point: The hospital meets the criteria as enumerated by the specific standard
- 2 Points: The hospital exceeds the criteria as enumerated by the specific standard by demonstrating (for example, but not limited to) more meetings, more quality improvement projects, etc.
- 3 Points: The hospital is considered exemplary against the criteria as enumerated by the specific standards by demonstrating (for example, but not limited to) more meetings with a specific percentage of attendance by particular personnel, more quality improvement projects which are shared outside of the organization, etc.

- Lowest Weight
  Event Rate Reporting: Event reporting is an important statement of quality and safety but tends to be less commonly applied. These should be more generally applied, but also include event rates that are specific to the episode when available.

Improvement Activity credit can be met based on the attestation of the development of a QI cycle using clinical data. These activities can be scored on a graduated scale based on their applied settings and their impact on PROMs or event rate reduction. More work is needed to define meaningful IA activities, settings, and roles played by the various actors within and across the episode. Facilities need to be engaged with activities and facilitate meetings with key staff who work with the clinical physician leads in defining the problem, the improvement activity, the data tracking, and outcomes reporting. These are elements of the verification/accreditation programs which would require periodic external review.

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[26] CMS Maternal Morbidity Structural Measure. Retrieved from: https://www.cms.gov/files/document/maternal-morbidity-structural-measure-specifications.pdf.
[27] BPCI Advanced Model Year 4 Quality Measures Factsheet. *Bariatric Surgery Standards for Successful Programs Measure*. Retrieved from: https://innovation.cms.gov/media/document/bpci-advanced-alt-fs-my4-bariatric.

Enhanced Performance Feedback in MVPs

CMS proposes to include comparative feedback within the annual performance feedback it provides MVP participants. The additional feedback will give MVP participants information on how their performance compares to similar clinicians who report on the same MVP.

The ACS appreciates CMS' efforts to provide physicians with more specific feedback about their performance in MVPs. However, we believe that the indicators CMS uses to show a physician's "quality" are confusing and lack meaningful metrics that drive improvements in care. The various feedback CMS provides through Care Compare, the annual performance feedback reports, and this newly proposed comparison among MVPs makes it difficult for physicians to determine where they should be focusing their efforts in the program.

CMS also asks stakeholders to elaborate on what they consider "actionable" information. This question is similar to questions the ACS receives from Fellows who participate in ACS Quality Programs. Everyone always intends to do their best, but when quality metrics reveal differences, it can be difficult to find a meaningful and actionable improvement activity.

As described, we believe that actionable information provides value to both the patient and the care team. It can be used to help patients make decisions about their care, as well as inform and educate clinicians on ways to continue to improve care and deliver value to patients. **Instead of offering physicians feedback on generic quality measures, we believe that CMS needs to focus on the care model, improvement cycles, the roles of the various actors, and the services delivered during an episode of care.** When a practice takes part in a certified quality program, they can assess the practice's infrastructure; how the care team's processes align to meet standards of care within a clinical domain; and gather interrelated, accurate, clinical, risk-adjusted outcomes data and PROs to highlight areas where further improvements are needed. With this information you can compare groups within the same specialties or compare clinicians based on the services they provide to assess their failure points and drive toward actionable fixes. If publicly reported, this information can also be useful for patients as they search for physicians. Patients would be able to search for physicians within a certain clinical domain or who delivers an episode of care and learn that the care team has efficient processes that comply with standards of care, receives a high patient experience score based on PROs, and delivers safe care through outcomes reporting.

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APM PERFORMANCE PATHWAY

In the CY 2021 PFS final rule, CMS finalized the APM Performance Pathway (APP). The APP was designed to provide a predictable and consistent reporting option for MIPS ECs who participate in a MIPS APM. Similar to MVPs, the APP includes a single, predetermined measure set clinicians can report on at the individual, group, or APM entity level. Participation in the APP is optional for all MIPS APM participants, however, all Medicare Shared Savings Program ACOs were required to report to the APP beginning with the 2021 performance period.

ACS applauds CMS for sunsetting elements of MIPS that have not driven quality improvement, but as mentioned in previous sections, we do not think the pathways that CMS is proposing to replace traditional MIPS—such as MVPs and the APP—are the solution. **As implemented, the APP is not a meaningful or relevant glidepath for surgical specialists in APMs because it focuses on primary care, similar to the CMS Web Interface measures. From the surgical perspective, the goal should be a framework that supports a comprehensive approach to quality that aligns with modern surgical care delivery and drives meaningful quality improvement efforts for surgical specialists in APMs.**

MIPS PERFORMANCE CATEGORY MEASURES AND ACTIVITIES

Quality Performance Category

Data Submission Criteria

When reporting traditional MIPS, a MIPS EC, group, or virtual group must submit data on at least six measures, including at least one outcome measure. This can be achieved by reporting Qualified Clinical Data Registry (QCDR) measures, MIPS clinical quality measures (MIPS CQMs), electronic CQMs (eCQMs), or Medicare Part B claims measures. CMS also developed administrative claims measures that are automatically evaluated and calculated (in addition to the six measures) for individual MIPS ECs, groups, and virtual groups if the case minimum of the measure is met. Beginning with the 2023 MIPS performance period, under the MVP proposal, CMS would allow an outcomes-based administrative claims measure to be selected when a MIPS EC registers for an MVP to fulfill the MVP outcome measure requirement.

CMS is also considering whether or how to allow and utilize outcome-based administrative claims measures to fulfill the outcome measure requirement within traditional MIPS. CMS seeks feedback on how it could automatically calculate an outcome-based administrative claims measure and apply it as one

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of the minimum six required measures, and if this would be an advantage for stakeholders as they participate in traditional MIPS.

The ACS thanks CMS for considering how to better utilize administrative claims-based measures. The ACS has continuously advocated that CMS measures should be collected, analyzed, and aggregated within a given domain or clinical service line by a single source for consistency in data interpretation. However, this has proved to be very difficult given how the MIPS measure system has been implemented, with multiple sources reporting the same measure inconsistently. **Most of the current MIPS measures do not ensure accurate benchmarking due to inconsistencies in program implementation and data interpretation; often using multiple data sources—included self-reported data—resulting in noisy metrics that are often not trusted by the physician community. Therefore, ACS supports the utilization of administrative claims measures as the single source for aggregation on a case-by-case basis and only for measures that have demonstrated reliability with claims data and are actionable in driving quality improvement cycles.**

Importantly, if CMS is the owner or "sole source" of the data for certain measures, it will be critical that there is transparency and consistency with the data definitions, appropriate inclusion/exclusion criteria, that data analytics are understood and standardized, that there is consistency in data ascertainment methods, and CMS is transparent in how data are normalized. By applying the appropriate measure science, CMS could create more reliable and valid comparisons in MIPS if the appropriate claims-based measures are chosen, compared to many of the current MIPS measures that are noisy.

As CMS develops these measures, the Agency should seek expert advice on the appropriate measures to report as part of an episode. Many outcome measures will require administrative claims data to be supplemented with clinical data for statistically valid results. The Agency should also seek expert advice to ensure that the data are meaningful and actionable for surgical practice and patients. For example, a measure that tracks readmission rates following a surgical procedure must include the proper exclusion/inclusion criteria. If a patient is admitted to the hospital for a motor vehicle accident unrelated to the patients' previous surgical procedure, this should not be included in the measure's numerator.

Group and Virtual Groups Reporting via the CMS Web Interface

In the CY 2021 Physician Fee Schedule Final Rule, CMS finalized the removal of the CMS Web Interface as an available collection and submission type

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under MIPS beginning with the CY 2022 MIPS performance period. In response to stakeholder comments and concerns about the difficulty of making this transition in light of the COVID-19 PHE, CMS proposed to extend the availability of the CMS Web Interface as a collection and submission type for the 2022 MIPS performance period and sunset the reporting mechanism beginning with the 2023 performance period. **In the past, ACS has raised concerns about how the measures required for groups reporting through the Web Interface could not effectively measure quality improvement in surgical care. However, we appreciate that CMS has listened to stakeholder concerns and is giving groups additional time to make the necessary updates to their reporting processes.**

Selection of MIPS Quality Measures

Each year CMS updates the quality measure set in the MIPS program by adding new measures, removing measures, and modifying the specifications of other measures. For 2022 MIPS performance period, CMS proposes a measure set of 195 MIPS quality measures. Below are comments to the General Surgery Specialty Measure Set:

General Surgery Specialty Measure Set

Beginning with the CY 2022 performance year, CMS proposes to remove two measures, *Selection of Prophylactic Antibiotic—first- OR second-generation cephalosporin* and *Perioperative care: VTE Prophylaxis*, from the general surgery specialty measure set. **As ACS has stated in previous sections, measuring stand-alone metrics have not been effective in achieving the goal of informing quality improvement cycles and driving real improvements in care. Therefore, we support a transition toward measures that do move toward that goal.** However, we caution CMS that removing some measures will make it more difficult for some groups—including surgical specialties—to succeed in the program. Given this, we recommend maintaining these measures until CMS has a clear plan for how they will replace them to give surgeons who are still required to report via traditional MIPS enough reporting options to avoid a MIPS-related penalty.

Cost Performance Category

Addition of Episode-based Measures

CMS proposes the addition of five new episode-based measures to the Cost performance category beginning with the 2022 performance period. The five proposed episode-based measures include:

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- Melanoma Resection;
- Colon and Rectal Resection;
- Sepsis;
- Asthma/Chronic Obstructive Pulmonary Disease (COPD); and
- Diabetes.

In prior comments to CMS, ACS has advocated for the need to measure cost and quality over the same episode of care to achieve higher value. Furthermore, for the Cost category of MIPS to be meaningful, the measures used must be not only reliable, but also actionable. That is, they should provide information on how a physician or care team currently uses resources and allows for comparisons with others who may be more efficient.

The ACS nominated three surgeons who took part in the colon and rectal resection measure development subcommittee. Based on ACS Fellows' experience during Wave 3 of measure development, the Acumen process for developing these measures is not structured to form measures that truly measure cost or offer actionable results. During the development process, subcommittees are required to follow a single, basic framework, regardless of condition or patient population. **We do not believe that physician cost, quality, and overall value can be evaluated using a one-size-fits-all approach. Procedures and patient populations are vastly different and cannot always be evaluated for appropriateness in the same manner.**

Another ongoing problem with the Acumen cost measure development process is that it relies exclusively on claims data. The limitations of administrative data interfere with risk stratification, subgrouping, and defining accurate and appropriate inclusion and exclusion criteria. Many have also had concerns about applying the CMS-Hierarchical Condition Categories (HCCs) risk adjustment methodology to these episode-based cost measures. The CMS-HCCs were not designed to risk-adjust narrowly defined patient cohorts, such as episode groups.

In addition, this approach to developing cost measures fails to account for the impact that cost reduction may have on patient outcomes or other measures of quality. It is virtually impossible for clinicians to evaluate, provide meaningful feedback on, and find significance in cost performance data when it is presented with no consideration of quality. While we acknowledge that CMS is working towards aligning cost measures with relevant quality measures through MVPs, the measures' set forth by CMS do not offer actionable information that can be used to incentivize reduction of costs.

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Finally, the current process lacks transparency. Until recently, CMS did not publicly release performance benchmarks for this performance category. Historically, this information has only been available through confidential feedback reports. Without current information, it is difficult for physicians to gauge how they might be scored in this performance category.

Proposed Process for Cost Measure Development by Stakeholders

CMS proposes to establish a process, beginning in CY 2022, for the development of cost measures by stakeholders, outside of the current development process. The process is intended to ensure that the cost performance category has consistency across measures, aligns with CMS priorities, and is consistent with the Meaningful Measures Framework.

The Measure Prioritization Criteria include:

- *Clinical coherence of measure concept (to ensure valid comparisons across clinicians).*
- *Impact and importance to MIPS (including cost coverage, clinician coverage, and patient coverage).*
- *Opportunity for performance improvement.*
- *Alignment with quality measures and improvement activities to ensure meaningful assessments of value.*

To ensure that cost measures developed by stakeholders meet the same standards as cost measures currently used in MIPS, CMS proposes to apply the following standards when considering stakeholder developed measures:

- *Measures must assign services that accurately capture the role of attributed clinicians.*
- *Measures must have clear, ex ante attribution to clinicians.*
- *Measures must be based on episode definitions that have clinical face validity and are consistent with practice standards.*
- *Measures' construction methodology must be readily understandable to clinicians.*
- *Measures must hold clinicians accountable for only the costs they can reasonably influence.*
- *Measures must convey clear information on how clinicians can alter their practice to improve measured performance.*
- *Measures must demonstrate variation to help distinguish quality of care across individual clinicians.*

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- *Measure specifications must allow for consistent calculation and reproducibility using Medicare claims data.*

The ACS welcomes the opportunity to develop and submit new cost measures for MVPs. However, as proposed in the *Standards for Measure Construction and the Measure Prioritization Criteria*, the opportunities to develop new measures will be constrained to largely mirror the structure and scope of the existing, ineffective episode-based cost measures. This will likely lead to measures very similar in nature to episode-based cost measures currently developed for the MIPS program. This may be intentional, but the lack of flexibility in approach to the measurement of the price paid for care will preclude innovative approaches which could be beneficial not only to MVPs but also in price transparency efforts and in alternative payment models. The existing MIPS cost measures are very narrowly defined, limiting their value for incentivizing reduction in cost within MIPS and for other purposes outside of the MIPS program.

Logically, and for the sake of efficiency, measurement of the price of care should align with existing and developing price transparency regulations so that information provided to patients to make informed decisions on their care is equivalent to feedback received by physicians for improvement purposes. Specifically, episode-based cost measures and information required by price transparency regulations should use common episode definitions. The alternative is a state of confusion for both physicians seeking to reduce cost and for patients seeking cost-efficient care.

As an example, consider a surgeon who, based upon the MIPS cost measure for colon and rectal resection, has an average cost performance score in MIPS. However, under the price transparency requirements, their costs appear 20 percent greater than the regional average because a broader array of items and services are considered. This inconsistency will lead to mistrust of information and unclear targets to reduce cost. Furthermore, this example can be expanded beyond the Medicare program where the same procedure performed by the same surgeon might not be in network for the prevailing insurer at the hospital where it is performed; meaning the costs would appear even higher in a good faith estimate for a typical patient under the requirements being proposed for the No Surprises Act.

If we intend to identify and reduce the cost of unnecessary, duplicative, or unwarranted aspects of care and to inform patients about the overall cost of care through price transparency, we should seek solutions that complement each other. There is no connection between the way we measure price for payment incentive purposes and the way we are proposing to measure

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it for transparency purposes. This is a missed opportunity that requires greater flexibility to allow for more comprehensive episode definitions that look at care from the perspective of the patient, rather than simply at charges under the direct control of a single physician. Measures that recognize the team-based nature of care with shared accountability are more appropriate if we expect to optimize the total care expenditure. CMS MIPS cost measures seek to constrain charges to what is substantially in the direct influence of a physician. The judgment applied to determine what is in the control of a specific physician is statistically 'noisy' at best because care delivery is typically team-based in modern healthcare.

Team-based episodes would be necessarily broader, with accountability shared among all of those who have influence over the care of the patient, the ultimate outcome, and cost of their care. If such a standard were adopted by the Medicare program, it would likely also be adopted in the private sector, allowing for more meaningful comparisons regardless of payor. For example, ACS is currently using price information derived from such episodes in our ACS THRIVE efforts (https://www.facs.org/quality-programs/acs-thrive). **Using a standard episode definition to measure the price paid by Medicare patients and beneficiaries for transparency purposes and then using the same standard for payment purposes—such as in the cost category of MIPS or in alternative payment models—would provide valuable, actionable information to physicians, payors, and patients alike.** The ACS price transparency efforts define an episode of care, such as colectomy for colon cancer. The price covers the services that are considered appropriate based on inputs from the teams of clinicians who treat such patients. In addition to the appropriate services, the episode definition database also includes all plausible services that may be associated with this episode. The plausible services are where the warranted versus unwarranted services reside. ACS also further defines the services assigned to an episode into pre-facility, in-facility, and post-facility price mappings. These reports allow for regional comparisons based on volume of services and mean or median overall price. In addition, the clinical teams can assess their pre-facility, in-facility, and post-facility differences to better understand the opportunity for reducing wasteful expenditures.

The approach taken by the ACS is used for other commercial activities. It is more reliable because it is clinically derived and attributes the best faith estimate of real or true costs to the episode of care. This approach is highly consistent with the Congressional intent behind price transparency and no surprise billing.

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Improvement Activities Performance Category

The IA performance category is included in MIPS with the intent of measuring provider engagement in activities that improve clinical practice. This performance category is reported via attestation and is worth 15 percent of the MIPS EC's final score.

The ACS believes that CMS has missed the mark in measuring clinicians' commitment to activities that drive real improvements in care. The IA category is undervalued and underappreciated in the current program because the category is designed for the sake of payment rather than the implementation of processes that use quality data to drive improvement. From the ACS perspective, quality metrics are a foundational element of a quality improvement program, but the overarching goal is to gather actionable data through the quality measures to drive improvements in patient care. **To this end, the ACS advocates for a program that allows for more cohesion between quality measurement and improvement cycles. The Improvement Activities category should simultaneously and seamlessly embody the improvement cycle that is driven by quality measures; if quality data is provided to physicians or groups but they are unable to facilitate improvements in care based on those metrics, then the measures are not effective.** The ACS acknowledges that CMS may be restricted by how the MACRA law defines the IA category, but we believe that to fully achieve the intent of the law, driving improvements in care requires the successful implementation of all elements of a quality program including structure, process, and outcomes that ultimately inform improvement.

To support ACS Quality Program participants, the ACS recently developed the Surgical Quality Improvement Course. The development of this course was in response to quality program participants who met the program standards and had access to high fidelity, risk-adjusted clinical data but they did not know what actions to take to improve. The surgical QI course aims to provide a quality improvement educational course for practitioners performing or overseeing improvement efforts including surgeons, trainees, and residency program directors to name a few. This course is part of the all-encompassing quality program. The ACS currently offers a basic course, which is broadly applicable to surgery, that teaches the key quality improvement concepts, the quality improvement process—including how to start a QI project, data measurement and analysis, including tools for current state and root cause investigation and data analysis, change management for QI, measuring patient safety, building a QI team, and fostering a culture of quality improvement. The College is also currently developing advanced courses which focus specifically

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on ACS Quality Programs, such as a Commission on Cancer course using National Cancer Database (NCDB) data, for example.

Improvement Activities Inventory

CMS proposes to modify five existing improvement activities to shift the focus toward health equity, as well as propose a new improvement activity titled "Create and Implement an Anti-racism Plan," which focuses on systemic racism as a root cause for differences in health outcomes between socially defined racial groups. CMS explains that the plan should include a clinic-wide review of existing tools and policies, such as value statements or clinical practice guidelines, to ensure that they include and are aligned with a commitment to anti-racism. The plan should also identify ways in which issues and gaps identified in the review can be addressed and should include target goals and milestones for addressing prioritized issues and gaps, which may also include development of an organization's plan to prevent and address racism and/or improve language access etc.

The ACS is committed to dismantling systemic racism in surgical care. We think the first step in addressing systemic racism might be to understand local economic and racial disparities and create a strategic plan to address health equity. One example of strategic work being done on the systems level is the Health Anchor Network (HAN), a noteworthy initiative which addresses economic and racial inequities through the influence health systems can have on a community. This work includes large and strategic investments in the hospital's local community, using a health system's economic power to inclusively and sustainably benefit the local community they serve—including hiring, purchasing, and investing locally. The HAN aims to "define the healthcare leadership standard and promote industry collaboration for proactively addressing economic and racial inequities in community conditions that create poor health." Many large healthcare systems including Kaiser, Rush, and Henry Ford, to name a few, are leading these efforts.

In response to the specific IA proposal, we are concerned that the implementation of a system-wide plan which calls for the development of a value statement, review of policies, improved language access and so on has a greater chance of success if done by department heads or the facility administration—not a single clinician or group. This is an example of how MIPS and MVPs fail to recognize the critical importance of how modern surgical care is delivered, including the critical role the facility plays. How would the Agency envision this IA being implemented by individual clinicians such as surgeons? Instead, the facility should provide the appropriate resources, infrastructure, and educational opportunities needed to create and

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implement any type of organizational plan. This could be part of the hospital incentive programs where the hospital attests to having and implementing an organizational plan and the individual clinician or group reports participating in the plan.

Promoting Interoperability Performance Category

The Promoting Interoperability (PI) performance category is one of the four required MIPS performance categories that is used to determine a MIPS final score for MIPS ECs. CMS has described the PI category as a way to promote patient engagement and electronic exchange of information using CEHRT. As the ACS has stated in the past, we urge CMS to look beyond EHRs as they continue to score physicians under this category. Technology is advancing into healthcare at a rapid pace. There is appreciation that EHRs are transactional workflows designed to document care and assure payment, while new technology solutions appreciate a patient's journey through the various points of care. Technology is exposing knowledge in patient workflows and in clinical workflows spanning the larger perspective of the patient's care journey. With each connection across the patient journey, data systems, not EHRs, are more complete representations of a patient. The focus has become one of knowledge sharing and knowledge engineering of digital services that will decrease burden, and help clinicians deliver improved patient care. **Instead of measuring the functionality of EHRs, CMS could consider how to measure the key aspects of shared knowledge. Measures could be built around the major elements of clinical informatics, which are defined by the American Medical Informatics Association (AMIA)**

The ACS also recommends that CMS work with other federal agencies, such as the ONC and Food and Drug Administration (FDA), to align their strategies on how to best promote the use of technologies that incorporate knowledge engineering digital services that can help physicians and patients reimagine how they manage care such as clinical decision support, clinical practice guidelines, predictive analytics, assessments and calculations such as in machine learning, and artificial intelligence. Knowledge engineering technologies would be able to assemble all relevant information about the patient's care history and display data such as operative reports, referring physicians' notes, medication histories, etc. to guide treatment decisions.

Proposed Changes to the Query of Prescription Drug Monitoring Program (PDMP) Measure under the Electronic Prescribing Objective

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CMS proposes to maintain the Electronic Prescribing Objective's Query of PDMP measure as an optional measure under the Electronic Prescribing objective. CMS also proposes to continue offering 10 bonus points for this measure for the CY 2022 performance period/2024 MIPS payment year to incentivize clinicians to perform queries of PDMPs. The Agency cites stakeholder concerns about the lack of PDMP integration in EHR workflows and wide variation of PDMP implementation across states. Because there are still many technical and operational concerns around how to optimize a query of the PDMP, CMS states that it does not feel that this measure should be required.

As stated in our past comments, the ACS agrees that this measure should not be required. Without the ability to seamlessly exchange data between EHRs and PDMPs, it is challenging to electronically report due to the additional documentation and verification with an external system. This creates unnecessary documentation burden for clinicians. We challenge CMS to consider how PDMPs can be optimized with knowledge engineering. Knowledge engineering solutions would be extremely helpful in tracking and analyzing narcotic prescribing practices and a patient's risk for Opioid Use Disorder (OUD). For example, a physician would input prescribing information for a certain patient into the patient's record, which could be sent directly from their EHR to the PDMP. Then the PDMP, through analytics built within the PDMP, could review the patient's record within the system and flag any variables that would signal the patient's risk for overuse or OUD. These analyzed data and any other variables the physician requests would then be sent back to the physician at the point of care to support clinical decision making. A system such as this could optimize PDMP's ability to exchange meaningful knowledge for better clinical care.
CMS also seeks feedback on whether this measure should be a required measure under the PI performance category in the future. Currently, there is wide variation in the sophistication of functionalities for each state's PDMP. Each state also has their own standards for their PDMP which has resulted in limited data sharing across state lines. **The ACS does not support that this measure be required until CMS can ensure that there is widespread uniformity in PDMPs across the country.**

Proposed Changes to the Provide Patients Electronic Access to their Health Information Measure Under the Provider Patient Exchange Objective

The *Provide Patients Electronic Access to their Health Information* measure under the Provider Patient Exchange Objective requires that for at least one unique patient seen by the MIPS EC:

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1. The patient is provided timely access to view online, download, and transmit his or her health information; and
2. The MIPS EC ensures the patient's health information is available for the patient to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS EC's CEHRT.

CMS proposes to revise this measure to require MIPS ECs to ensure that the patient's health information is available to the patient to access indefinitely using the application of their choice. The current measure does not specify how long clinicians are required to make patient data available or ensure that the patient data remains available to the patient should the clinician switch EHR vendors. The proposed requirement would begin with the 2022 performance period and include all patient health information from encounters on or after January 1, 2016.

The ACS is generally supportive of giving patients more access to and control of their electronic health information. However, **we ask that CMS provide more clarity on how they plan to define the "indefinite" period in which a provider would be required to make patient health information available.** Currently, practices must comply with the time periods for record retention as described in federal and state law. In this proposal, it is unclear how long a practice would have to continue storing patient records after their practice closes or the patient transfers to a different physician, for example. If a practice is required to maintain electronic records indefinitely, they would still have to maintain costly data storage space even after the practice's doors have closed. **Given this, the ACS recommends that CMS should not finalize this proposal, and should provide further clarity before imposing these requirements. If CMS chooses to go forward with implementing this measure, we suggest that CMS delay the inclusion of this measure until clinicians are required to begin utilizing EHRs certified to the 2015 Edition Cures Update to report in the PI category.** We believe that the functionalities required by the updated version of CEHRT will further enhance practices' ability to seamlessly transfer EHI between different systems.

Modifications to the Public Health and Clinical Data Exchange Objective

Currently, a MIPS EC must submit a yes/no response for two different public health agencies or clinical data registries for any of the five measures associated with the Public Health and Clinical Data Exchange objective to earn 10 points for the objective. Beginning with the CY 2022 performance period, CMS proposes to require two of the measures associated with this objective:

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- Immunization Registry Reporting; and
- Electronic Case Reporting.

CMS believes these two measures would allow public health agencies to be better prepared for future health threats and a long-term COVID-19 pandemic recovery through vaccine update and case surveillance.

In addition, CMS proposes that beginning with the CY 2022 performance period, a MIPS EC would receive 10 points for reporting a "yes" response for each of the two required measures. CMS also proposes to retain the Public Health Registry Reporting, Clinical Data Registry Reporting, and Syndromic Surveillance Reporting measures as optional measures and available for bonus points. A MIPS EC may earn five bonus points if they report a "yes" response for any one of these three bonus measures.

The ACS supports CMS' efforts to help public health organizations better prepare future public health emergencies and the long-term effects of the COVID-19 pandemic through the *Immunization Registry Reporting* and *Electronic Case Reporting measures*. We also thank CMS for maintaining the Clinical Data Registry Reporting measure within this objective and offering bonus points for those who report to clinical data registries. Many clinical data registries have implemented mechanisms to gather data about the impact of COVID-19 and will be good sources of information when determining how different clinical specialties were ultimately impacted by the COVID-19 pandemic.

SAFER Guides

The Safety Assurance Factors for EHR Resilience Guides (SAFER) guides were developed by ONC in 2014 and updated in 2016. The guides assist hospitals in conducting self-assessments to optimize the safety and safe use of EHRs in three main areas: foundational guides, infrastructure guides, and clinical process guides. CMS proposes to add a new measure to the Protect Patient Health Information objective, beginning with the CY 2022 performance period. The new measure would require MIPS ECs to attest to having completed an annual self-assessment using the High Priority Practices Guide at any point during the calendar year with a yes/no attestation statement. In CY 2022, this measure would be required, but it would not be scored, and that reporting "yes" or "no" will not affect the total score for the Promoting Interoperability performance category.

The ACS feels that the SAFER guides are comprehensive, but in some cases several of the assessments contain information that should be the responsibility of the vendor to meet and complete, rather than the

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hospital; specifically, the items in the High Priority Practices Checklist. Then, instead of requiring individual clinicians to complete these assessments, the ACS recommends that CMS should require the health IT vendor complete the assessment when they complete the implementation of the health IT. This should be done on a regular basis to ensure the systems continue to meet the safety requirements of these guidelines as the health IT software undergoes regular system updates. **In addition, the ACS suggests that CMS and ONC consider reviewing and updating the SAFER guides as they have not been updated since 2016.** The digital health landscape is constantly transforming, and these guides should be updated to ensure that they include possible patient safety threats that could stem from increased interoperability and new technologies.

Actions to Limit or Restrict the Compatibility or Interoperability of CEHRT

Beginning with the CY 2022 performance period, CMS proposes to no longer require attestation statements B and C of the existing Information Blocking attestations. CMS believes that the below statements can be removed in light of the information blocking regulations finalized in the ONC 21st Century Cures Act final rule.

- Statement B: Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: (1) Connected in accordance with applicable law; (2) compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria; (3) Implemented in a manner that allowed for timely access by patients to their electronic health information; and (4) Implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers, including unaffiliated providers, and with disparate certified EHR technology and health IT vendors.
- Statement C: Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers and other persons, regardless of the requestor's affiliation or technology vendor.

While the ACS agrees that it is acceptable to remove these attestations in light of the recently implemented 21st Century Cures Act final rule information blocking regulations, we want to highlight the importance of the information blocking issue. The ACS remains concerned that without

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the proper oversight, challenges with information blocking will persist. As the health care system continues to implement pathways for standards-based bidirectional exchange of EHI, health IT vendors have created proprietary platforms that place a major financial burden on physicians, clinical data registries, and those developing digital health platforms, such as specialty societies. For example, if a specialty society develops a digital health platform that supports clinical data registries and quality programs, they would be required to enter expensive financial agreements with EHRs' proprietary platforms to access EHI and integrate those data into their systems. Placing monopolistic barriers on "read" and "write" capabilities should be considered data blocking as such barriers will restrict the interoperability needs for advance knowledge management. **We request that CMS respond with details on what the Agency is doing, along with ONC, to address this issue.**

Reweighting the PI Category for MIPS eligible clinicians in small practices

In past years, MIPS ECs in small practices (a TIN consisting of 15 or fewer ECs) could qualify for reweighting of the PI category through an application-based significant hardship exception. Beginning with the CY 2022 performance period, CMS proposes to no longer require an application for clinicians and practices seeking to qualify for a small practice hardship exception and reweighting. Instead, in the event that no data is submitted for any of the measures for the PI category by or on behalf of a MIPS EC in a small practice, CMS would assign a weight of 0% to the PI category and redistribute its weight to another performance category. **The ACS supports this proposal. Automatically reweighting the PI performance category for small practices will reduce unnecessary administrative requirements and support small practices as they work to meet the performance threshold and avoid a negative payment adjustment.**

<u>Performance Category Scores</u>

Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmark Requirements

CMS proposes multiple updates to the quality measure scoring policies beginning with the CY 2022 performance year. In past years, quality measures that have benchmarks, meet the case minimum requirements, and meet the data completeness requirements were given a 3-point floor. CMS also gave physicians three quality measure points if they reported quality measures that do not have a benchmark or do not meet the case minimum requirement. CMS proposes to remove these scoring floors for both types of quality measure beginning with the CY 2022 performance period. This means that for measures

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with benchmarks that meet the case minimum and data completeness requirements, physicians will receive 1 to 10 points towards their quality category score. In addition, should these policies be finalized, physicians who report measures that do not have benchmarks or meet the case minimum would receive zero points towards their quality category score, unless they are part of a small practice, who will still receive three points for these measures.

In the proposed rule, CMS also states that they do not want to discourage physicians from reporting new measures, so they are proposing a 5-point floor for quality measures that are new to the program for all collection types for their first two years in the program. How CMS proposes to score these measures is included below:

- New measures that can be reliably scored against a benchmark because they meet the data completeness requirement, can have a performance period benchmark calculated, and meet case minimum requirements will be scored from 5 to 10 measure achievement points.
- New measures that cannot be reliably scored against a benchmark because they lack a benchmark or do not meet case minimum but meet the data completeness requirement will receive a score of five.
- New measures that cannot be scored because they do not meet the data completeness requirement will receive a score of zero for clinicians other than small practices, while small practices will continue to receive three points.

In general, the ACS is supportive of efforts to incentivize the use of new quality measures in MIPS. We believe this will allow for greater utilization of innovative measures that show evidence of driving improvements in care. We also ask CMS to consider how they will evaluate the measures that have been in the program for multiple years and have not had a benchmark. While some of these measures may not be the "right" measures for a quality improvement program and should not be incentivized or maintained, there may be measures that might provide valuable information, but have gone unreported because of low scoring potential. Keeping this in mind, we ask that CMS, with stakeholder input, also incentivize reporting for existing measures if their outputs are proven to drive improvement.

Calculating the Final Score

Complex Patient Bonus

The complex patient bonus was introduced in the CY 2018 QPP final rule. Initially the complex patient bonus would add up to five bonus points to a

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MIPS EC's final score, and the bonus is determined through a calculation that accounts for medical risk through the HCC risk score, and social risk by measuring the proportion of patients that are dually eligible for Medicare and Medicaid. CMS has stated that they intended for the complex patient bonus to be a short-term strategy to address the impact that patient complexity might have on MIPS scoring while they worked with stakeholders to establish a methodology that better captures patient risk factors. For the CY 2022 performance period, CMS proposes to revise the complex patient bonus formula so the complex patient bonus better targets clinicians who treat a higher caseload of complex and high-risk patients. CMS makes five separate proposals to revise the complex patient bonus beginning in CY 2022, these proposals are as follows:

- The complex patient bonus will be added to the final score for the MIPS payment year provided that the MIPS participant(s) submits data for at least one MIPS performance category during the applicable performance period.
- The complex patient bonus is limited to MIPS ECs, groups, subgroups, APM entities, and virtual groups with a risk indicator at or above the risk indicator calculated median.
- For MIPS ECs, groups, and subgroups, the complex patient bonus components—medical complexity and social complexity—are calculated for the specific risk indicators. The components are then added together for one overall complex patient bonus. CMS will also use a standardized score for each risk indicator to determine how far the risk score is from the mean.
- For APM entities and virtual groups, the complex patient bonus components—medical complexity and social complexity—are calculated for the specific risk indicators. The components are then added together for one overall complex patient bonus. CMS will also use a standardized score for each risk indicator to determine how far the risk score is from the mean.
- The complex patient bonus cannot exceed 10.0 and cannot be below 0.0

The ACS supports the goal of improving care of complex patients and appreciates CMS' efforts to acknowledge physicians who care for more complex patients. Over time these patients will likely require more resources from the system, and it is important to appropriately align incentives so that teams who demonstrate improved care of complex patients are rewarded. This is critical to improve access to care for complex patients.

While we consider the MIPS complex patient bonus more closely targeting physicians who care for the most complex patients a worthy effort, we have

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two major concerns with both the clinical risk and social risk indicators. Using the HCC on CMS administrative claims data alone is insufficient. Clinical data is much more reliable for determining comorbidities and should be used alongside administrative claims data. Additionally, using dual-eligibility as the sole indicator of social risk does not capture the full scope of patients who might have risk factors that contribute to the complexity of care they need, possibly reducing access for those who do not fit that definition. Only approximately 20 percent of the Medicare population falls within the dual-eligible designation, but we can assume that there are many more patients that have significant condition-specific or social risk factors that contribute to their need for more complex care even though they are do not meet the dual-eligible definition. Again, by using the dual-eligible designation as the only social indicator, we are concerned access to care may be impacted for those who do not fit that definition. **Identifying patients who will require complex care is a complicated task in itself, as we have outlined in our responses to the "Closing the Health Equity Gap" RFI, therefore the ACS asks that CMS continue to work with stakeholders to design a more inclusive and accurate method to provide rewards to clinicians who treat complex patients. We also ask CMS to consider more reliable ways to further reward teams who can demonstrate improvements in care while also serving complex patients, beyond the simple tool of bonus points.**

The ACS appreciates the opportunity to provide feedback on this proposed rule and looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Vinita Mujumdar, Regulatory Affairs Manager, at vmujumdar@facs.org, or Jill Sage, Quality Affairs Manager, at jsage@facs.org.

Sincerely,

David B. Hoyt

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1921 HAP 2021
100 YEARS TOWARD BETTER HEALTH

Leading for Better Health

September 13, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

SUBJECT: CMS-1751-P. Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements; Proposed Rule, August 23, 2021

Dear Administrator Brooks-LaSure:

On behalf of The Hospital and Healthsystem Association of Pennsylvania (HAP), which represents approximately 240 member institutions, we appreciate the opportunity to comment about the Centers for Medicare & Medicaid Services' (CMS) Medicare Physician Fee Schedule proposed rule for calendar year (CY) 2022.

HAP is pleased to see the agency's continued efforts to retain important telehealth flexibilities permitted during the COVID-19 pandemic but concerned with the proposals made impacting payment for office/outpatient evaluation and management (E/M) visits.

The following comment letter also addresses:

- Appropriate Use Criteria
- Opioid Use Disorder Treatment Services
- Changes to quality programs

We have also taken the opportunity to include reference to the very important work Pennsylvania hospitals are undertaking with respect to health equity.

In addition, we incorporate, by reference, all of the comments provided in the American Hospital Association's response to the proposed rule.

Thank you for your consideration of HAP's comments regarding this proposed rule. If you have any questions, contact Kate Slatt, vice president, innovative payment and care delivery, at (717) 561-5317.

Sincerely,

Jeffrey Bechtel
Senior Vice President, Health Economics and Policy

Attachment

1921 2021
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Leading for Better Health

HAP Comments—Physician Fee Schedule
Proposed Rule for Calendar Year 2022

Payment for Evaluation and Management Visits

In this rule, the Centers for Medicare & Medicaid Services' (CMS) continues its efforts to refine the current Evaluation and Management (E/M) payment system and is proposing changes to the following:

- "Split" or shared E/M visits
- Critical Care Services
- Teaching Physician Services

"Split" E/M Visits: Split visits occur when both a physician and a non-physician provider (NPP) provide services during an E/M visit. In this rule, CMS proposes to define "substantive portion" as more than half of the total time spent by the physician or the NPP. CMS further proposes that the distinct time of services spent by each physician or NPP furnishing a split visit would be summed to determine total time of the visit. This would establish who provided the substantive portion of the visit and would therefore bill for the service.

If a physician performs a substantive portion of the visit, they can bill for the E/M and receive Medicare payment equal to 80 percent of the otherwise applicable payment of the Physician Fee Schedule, which is the lesser of the actual charge or the fee schedule amount for the service. If the NPP performs a substantive portion of the visit and therefore bills for the service, payment is 80 percent of the lesser of the actual charge or 85 percent of the fee schedule rate.

Critical Care Services: CMS is proposing several changes related to critical care visits including:

- Adopting the prefatory language of the Current Procedural Terminology Professional Codebook that defines critical care and delineates where, when, and by whom critical care may be delivered
- Define concurrent care as more than one physician or qualified NPP furnishing services to the same patient on the same day
- Allow critical care services to be furnished as concurrent care if medically necessary and not duplicative
- No other E/M visit can be billed for the same patient on the same date as a critical care service when the services are furnished by the same practitioner, or by practitioners in the same specialty and same group
- Bundle critical care visits with procedure codes that have a global surgical period

Teaching Physician Services: As part of its changes to E/M visit coding last year, CMS permitted the use of medical decision-making (MDM) or time spent to select and bill for appropriate E/M visits. In this rule, CMS is proposing that when total time is used, only the time that the teaching physician is present may be considered.

CMS also proposes a change to the "primary care exception," which allows for payment in some teaching hospital primary care centers for certain lower complexity services when performed by a resident without the presence of a teaching physicians. CMS proposes to only allow MDM in determining the appropriate E/M visit rather than also allowing time in these circumstances.

There are significant consequences related to the proposals governing payment for certain E/M services as outlined above. The current proposal related to split billing does not take into account how clinical workflows are structured. This proposal also directly contradicts former efforts to reduce administrative burden and will cause significant patient flow inefficiencies at a time when the strain on the health care workforce has never been greater, and the need for patient care has never been more urgent in the wake of COVID-19.

HAP urges CMS to resist finalizing the split visit proposal in which "substantive portion" is based on time. As has been the practice, medical decision-making should determine the appropriate level of E/M visit.

HAP also urges CMS to withdraw its proposals related to critical care visits including the bundling of critical care visits with procedure codes that have a global surgical period until further evaluation can be conducted on unintended consequences.

Telehealth

Category 3 Services: As a result of the COVID-19 pandemic, CMS added multiple services to the Medicare telehealth list for the duration of the emergency. CMS is proposing to make some of these additions permanent.

Prior to CY 2021, Medicare had two criteria categories for assessing requests for adding or deleting services from the Medicare telehealth list of services under Section 1834(m) of the Social Security Act:

- Category 1 are services similar to other services already on the Medicare telehealth list
- Category 2 are services that are not similar and, therefore, require additional supporting evidence of clinical benefit

In the CY 2021 final rule, CMS created a new category. Category 3 describes services added during the Public Health Emergency (PHE) for which there is clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence to consider the service as permanent additions under Category 1 or 2 criteria. Category 3 services are to remain on the telehealth list until the end of the PHE.

Undoubtedly, the COVID-19 pandemic has created a world of uncertainty for patients and their health care providers. CMS recognizes this uncertainty and the impact the end of the PHE might have on Category 3 services and proposing to retain all Category 3 services until the end of CY 2023.

Geographic Limitations: The Consolidated Appropriations Act of 2021 (CAA) waived the long-standing geographic limitations placed on the provision of telehealth services and also added the patient's home as an originating site for purposes of diagnosis, evaluation, or treatment of a mental health disorder. In this rule, CMS is proposing that providers conduct in-person services within six months prior to providing an initial mental health telehealth service, and at least once every six months thereafter. This is specifically for mental health telehealth services made possible by the CAA—patients receiving mental health services in their homes and those patients in geographic locations beyond those currently authorized for Medicare telehealth services.

Audio-Only Telehealth Services: CMS also acknowledges the importance that allowing for audio-only mental health telehealth services have had during the PHE. In this rule, CMS proposes to amend the definition of "interactive telecommunications system" to include audio-only communication when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients when the originating site is the patient's home. However, CMS is limiting payment for these audio-only services to providers with the capability to furnish two-way, audio/video telehealth services but are not doing so due to beneficiary technology limitations or preferences.

Direct Supervision: In the CY 2021 Physician Fee Schedule Rule, CMS finalized its proposal to extend the allowance for physicians and NNPs to provide direct supervision via audio/video technology through the end of the calendar year in which the emergency ends or December 31, 2021, whichever is later. CMS is seeking comment about whether it should temporarily continue beyond the timeline above or be made permanent.

While a grim reality, the PHE has been the impetus for advancing access to health care through technology tenfold. Beneficiaries have been able to continue to see their health care provider and do so safely from the comfort of their own homes and will continue to demand access to telehealth. The Pennsylvania hospital community is eager to continue working with policymakers at the federal and state level to leverage the experiences of the pandemic and preserve expanded access to care through telehealth, when clinically appropriate.

HAP appreciates the significant actions that CMS is taking in this proposed rule, especially:

- Retaining Category 3 services through the end of CY 2023 regardless of the end of the PHE
- Making audio-only mental health telehealth services permanent

HAP urges CMS to make broad, permanent adoption of any services that were acceptable during the pandemic, given that only services that did not pose significant patient safety concerns were added to the list during this time. As such, we strongly support retaining Category 3 services through the end of CY 2023 and further suggest maintaining Category 3 as a permanent category. HAP also strongly supports making audio-only mental health telehealth services permanent as it has

become such a critical way to provide access and deliver these important services to beneficiaries.

While we strongly support the broadened originating site definition for coverage for mental health telehealth services, we also recommend additional analysis related to the requirement for in-person visits within six months of a telehealth service. This may be a barrier in treating Medicare beneficiaries who have become quite comfortable and satisfied in receiving their mental health services using telehealth capabilities.

HAP urges CMS to permanently allow direct supervision via audio/video technology.

Finally, while we appreciate the importance that telehealth has had in caring for patients with mental health needs and appreciate the attention CMS has given to these services, HAP urges CMS to make similar flexibilities available to non-mental health services.

Appropriate Use Criteria Program

CMS has been in the process of implementing the Appropriate Use Criteria (AUC) program for advanced diagnostic imaging during the past several years. During 2020, CMS began the educational and operations testing period. While testing, CMS continued to pay claims whether or not they correctly included AUC information. Testing was extended through 2021 as a result of the PHE.

Payment penalties were slated to begin January 1, 2022, however in consideration of the ongoing PHE, CMS is proposing to delay this phase until January 1, 2023, or the first of the January that follows the end of the PHE.

HAP fully supports the delay of the penalty phase of the AUC program and appreciates CMS' acknowledgement of the ongoing challenges the PHE has created.

Opioid Use Disorder Treatment Services

As a result of the PHE, CMS issued an interim final rule on April 6, 2020, that allowed opioid treatment programs (OTP) to furnish counseling and therapy services using audio-only telephone calls for the duration of the PHE. In this rule, CMS is proposing to allow for continued audio-only telephone services in cases where audio/visual technology is not available to the beneficiary—defined as circumstances where beneficiaries are not capable or have not consented to the use of devices that permit a two-way, audio/visual interaction.

CMS will require the addition of modifier 95 and a new modifier that will indicate the provider had the capability of providing audio and visual services but used audio instead after the

conclusion of the PHE. These requirements will begin January 1, 2022, or at the conclusion of the PHE if that is after January 1, 2022.

HAP strongly supports CMS' proposal to allow for continued audio-only telephone services at the conclusion of the PHE as it has become such a critical way to provide access and deliver these important services to beneficiaries.

Changes to Quality Programs

The CY 2020 rule introduced the general framework for future Merit-Based Incentive Payment System (MIPS) Value Pathways (MVP) that CMS believes would align and reduce reporting requirements across the four MIPS performance categories and intended to include specific MVPs in the CY 2021 rule. Due to the PHE, CMS delayed the introduction of MVPs until at least CY 2022, but emphasized its commitment to the intended phase- in of MVPs over time.

In this rule, CMS proposes implementing seven optional MVPs beginning with the CY 2023 performance period. Specifically, the MVPs include:

- Rheumatology
- Stroke care and prevention
- Heart disease
- Chronic disease management
- Lower extremity joint repair
- Emergency medicine
- Anesthesia

The rule also proposes additions to MVP development criteria, MVP eligibility and registration process, reporting requirements, and scoring approach for MVP participants.

HAP supports the consideration that CMS has given to the impact of the PHE in implementing the MVPs and appreciates the voluntary nature of the implementation, however, HAP urges CMS to refrain from setting a date to begin implementation until it addresses several issues including but not limited to:

- ***Including applicable measures for the wide range of specialty types participating in the MIPS***
- ***Ensuring fair and equitable scoring across clinician, group types, and specialties***
- ***Ensuring minimal administrative burden for multi-specialty group practices***

CMS is continuing its efforts to refine the MIPS an incentive program for eligible clinicians that results in positive or negative payment adjustments of up to 9 percent during CY 2023 based on CY 2021 performance.

Specifically, CMS proposes the following:

- Quality Category: CMS proposes to lower the weight of the quality category 30 percent during CY 2022 to reach the statutorily mandate

- Cost Category: CMS proposes to increase the weight of the cost category to 30 percent during CY 2022 to reach the statutorily mandate

- Improvement Activities Category: CMS proposes to include a new improvement activity, "create and implement an anti-racism plan," modify five existing improvement activities to focus on health equity, and update the complex patient bonus formula to include a social complexity component

- MIPS Final Score Thresholds: CMS proposes to double the complex patient bonus to a maximum of ten points for the CY 2021 reporting period

HAP continues to have significant concerns with proposals related to the cost performance category including increasing the weight of the category.

HAP urges CMS to produce detailed feedback containing actionable data related to the measures included in the cost category. HAP also urges CMS to refrain from increasing the weight of the cost category until existing concerns with methodology related to current cost measures are fully addressed and the impact of the PHE can be fully understood.

HAP strongly supports CMS' efforts to include activities promoting health equity and anti-racism in the MIPS program. Pennsylvania hospitals are committed and engaged in efforts to close health equity gaps. Including this in the quality program allows for further focus and engagement in these critical activities.

HAP supports doubling the complex patient bonus in consideration of the significant effort hospitals have been making in navigating the management of these patients during a PHE.

HAP continues to urge CMS to ensure that appropriate risk adjustments based on clinical complexity and sociodemographic factors are incorporated in all aspects of the MIPS.

Medicare Shared Savings Program

In response to comments made regarding last year's Medicare Shared Savings Program (MSSP) proposals specifically related to reporting electronic clinical quality measure/MIPS clinical quality measure (eCQM/MIPS CQM) all-payor quality measure under the Alternative Payment Model (APM) performance pathway (APP), CMS is proposing a longer transition by extending the

availability of the CMS Web Interface collection type for two years through CY 2023 performance year.

The rule also notes that, for CY 2022 performance year, accountable care organizations (ACO) would be permitted to report either the current MSSP measure set via the CMS web interface, or the MISP APP measure set. During CY 2023, ACOs that chose the Web Interface measure set also would be required to report at least one measure from the APP measure set. Additionally, CMS is proposing a freeze of one year to the minimum quality performance standard from 30 to 40 percentile. The new minimum would be effective during CY 2024 rather than CY 2023.

HAP supports CMS' efforts to create a longer transition for reporting eCQM/MIPS CQM by maintaining the availability of the CMS Web Interface collection option but ask that CMS remove the requirement for the reporting of one measure from the APP measure set during CY 2023.

HAP also supports the delay of increasing the minimum quality performance standard for one year.

Health Equity Request For Information

CMS recently has used the Inpatient Prospective Payment System rulemaking process to expand the role of quality measurement to identify inequities. In this rule, CMS is requesting additional information relating to its work to advance health equity.

While there have long been clear signs of disparate health outcomes, this issue became glaringly apparent during our nation's efforts to combat the COVID-19 PHE. This has created a "call to action" and Pennsylvania's hospitals are responding.

HAP has been working collaboratively with members and the Pennsylvania Department of Human Services to introduce a new hospital quality incentive program aimed at addressing health inequities and racial disparities. Initially, the program will focus on implementing pathways that incentivize:

- Creating and implementing a structured race, ethnicity, and language (REaL) data collection process
- Using REaL data to identify gaps and address inequities
- Screening and identifying social needs and social risks
- Convening internal and external stakeholders to identify opportunities to close gaps

The expressed goal of the program is to improve disparate outcomes stratified by race related to preventable admissions.

In addition to working with the state to create programs for hospitals to begin to address this issue, HAP also is embarking on the launch of a new Racial Health Equity Learning Action Network that will bring Pennsylvania hospitals together to share best practices related to the meaningful work being done on health equity in this state.

Pennsylvania hospitals also have been actively participating across other initiatives as well, including:

American Hospital Association 123 Equity Pledge

During 2015, the American Hospital Association launched its #123forEquity pledge campaign, which built on the efforts of the National Call to Action to Eliminate Health Care Disparities. More than 1,650 hospitals, including 49 Pennsylvania hospitals and health systems, pledged to take action to eliminate health care disparities. In the pledge, member hospitals and chief executive officers committed to taking action to accelerate progress related to the four areas of the initiative's call to action:

- Increasing the collection and use of race, ethnicity, and language preference data
- Increasing cultural competency training
- Increasing diversity in governance and leadership
- Improving and strengthening community partnerships

Philadelphia Area Hospitals' Commitment to Anti-Racism

Thirteen of HAP's southeastern Pennsylvania hospitals and health systems recently announced a collective commitment to combat racism, inequality, and discrimination in all its forms. Stating that racism is a health care issue and explicitly acknowledging that systemic racism drives the socioeconomic factors that are barriers to health care access, cosigners committed to:

- Re-examining policies and procedures and making changes, with an equity lens, that promote equality, opportunity, and inclusion for all
- Improving access to primary and specialty care for people in underserved communities
- Building trust through community partnerships with the goal of addressing chronic conditions that impact communities of color
- Advocating for investments that create innovative solutions to improve access, and provide safe, high-quality health outcomes for all communities in Pennsylvania
- Hiring and promoting leaders of color and increasing diversity in governance
- Renewing and expanding each organization's commitment to providing anti-racism and implicit/unconscious bias training for all staff, volunteers, and physicians
- Bridging relations between law enforcement and community by offering events aimed at encouraging conversations, improving relations, and creating trust
- Increasing the collection and use of race, ethnicity, language preference, and other socio-demographic data

HAP supports CMS' efforts to improve health equity through its quality programs as one prong of a multi-prong strategy. While the delivery of health care is vitally important in health equity, significant thought and investment must also be made to evaluate and address broader community resources and needs.

Association of Black Cardiologists, Inc.
Saving the Hearts and Minds of a Diverse America

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Washington, DC 20037

(800) 753-9222
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ABC MISSION:
To promote the prevention and treatment of cardiovascular disease, including stroke, in Blacks and other minorities and to achieve health equity for all through the elimination of disparities.

September 13, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20001

Re: File Code CMS–1751–P. Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

Dear Administrator Brooks-LaSure:

On behalf of the Association of Black Cardiologists (ABC), we appreciate the opportunity to provide comment on the CY 2022 Medicare Physician Fee Schedule (PFS) proposed rule, published in the *Federal Register* on July 23, 2021, and specifically on proposed clinical labor price inputs and the request for information on closing the health equity gap in CMS clinician quality programs.

Founded in 1974, the ABC is a nonprofit organization with a national and international membership of 2,023 cardiovascular specialists, cardiologists-in-training and other health professionals, as well as professionals outside of health care who are 'lay' members of the community (Community Health Advocates) and corporate and institutional members. The ABC is dedicated to eliminating disparities related to cardiovascular disease for all people of color and adheres to the vision that all people regardless of race, ethnicity or gender should benefit equally from reduction in the frequency, duration and impact of diseases of the heart and blood vessels.

CLINICAL LABOR PRICE INPUTS

In the CY2022 PFS proposed rule, CMS proposes updates of clinical labor pricing using the 2019 United States Bureau of Labor

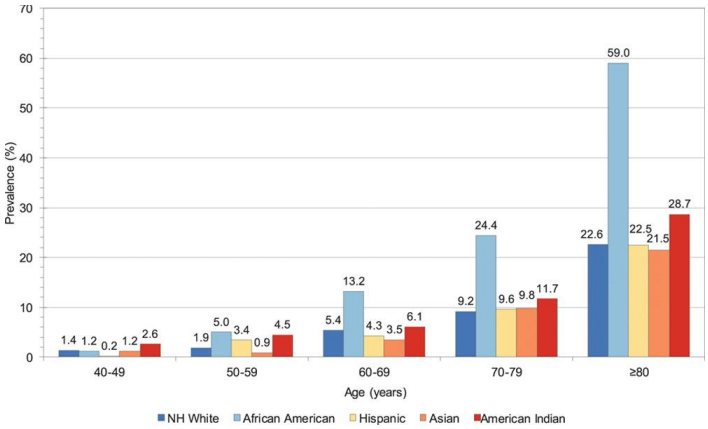
Statistics wage data. Because the clinical labor pricing has not been updated since 2002, the result is a significant budget neutrality adjustment. **We ask CMS to not finalize for CY 2022 the new proposed clinical labor pricing updates, and, in absence of reforms to the Medicare physician payment system, updates to clinical labor pricing should occur, at a minimum, over a four-year transition period. We also ask CMS to update pricing data on a more frequent basis for all inputs, so adjustments are not dramatic.**

Because of budget neutrality requirements, physician services with high-cost supplies and equipment are penalized even though labor costs for these services have also increased. And without a positive update to the conversion factor, the real increase in clinical labor costs is not recognized.

The COVID-19 pandemic has accelerated the number of physicians employed by hospitals or corporate entities. Consolidation has shown to increase health care spending, and the impact of corporate ownership of physician practices and its contribution to health inequities must be considered. According to testimony delivery at March 2021 hearing held by the House Ways and Means Committee, private equity-owned hospitals tend to be in more rural areas and, without oversight of otherwise questionable business structures, vulnerable populations are exposed. Reductions in reimbursement, payment unpredictability, and increased administrative cost and burden are pushing physicians toward hospital or corporate employment, which may be to the detriment of patient care.

Among the services that will experience a significant reduction in reimbursement are peripheral artery disease (PAD) / revascularization services (codes 37225-37221). PAD, a frequent complication of diabetes, affects more than 30 million Americans,[1] with African Americans more than twice as likely to have PAD than their white counterparts.[2] PAD develops when arteries become clogged with plaque resulting in reduced blood flow to the legs which puts patients at a dramatically higher risk of limb amputation, and this condition is often associated with disease in other blood vessels in the body resulting in the concomitant risk of a heart attack or stroke. Risk factors for amputation were evaluated in 2,730,742 Medicare beneficiaries ≥65 years of age with PAD using data from 2000 to 2008. Black race and diabetes each accounted for roughly 30 percent of the multivariable-adjusted logistic model for predicting lower-extremity amputation and had an OR of 2.9 and 2.4, respectively.[3] PAD treatment often involves lifestyle changes and medication; yet, only 20-30 percent of patients with PAD are being treated.[4] Revascularization often becomes necessary to improve the blood circulation to the legs to prevent amputation.

[1] American Diabetes Association https://www.diabetes.org/resources/statistics/statistics-about-diabetes
[2] Department of Health and Human Services https://www.nhlbi.nih.gov/health/educational/pad/docs/pad_extfctsht_general_508.pdf
[3] Jones WS, Patel MR, Dai D, Subherwal S, Stafford J, Calhoun S, Peterson ED. Temporal trends and geographic variation of lower-extremity amputation in patients with peripheral artery disease: results from U.S. Medicare 2000-2008. J Am Coll Cardiol. 2012;60:2230–2236. doi: 10.1016/j.jacc.2012.08.983
[4] Dhaliwal G, Mukherjee D. Peripheral arterial disease: Epidemiology, natural history, diagnosis and treatment; Int J Angiol. 2007 Summer; 16(2): 36–44. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2733014/



Estimates of prevalence of peripheral artery disease in males by age and ethnicity, United States, 2000. NH indicates non-Hispanic. Source: Data derived from Allison et al.[5]

If PAD is caught in time, and the patient is referred in a timely manner, significant benefit can be derived from a peripheral vascular intervention. This involves a vascular specialist performing an angiogram to assess the blood flow to the limb, identifying vessels narrowed by plaque, and restoring blood flow to the limb by special techniques. If blood flow is restored and an existing wound is given time to heal before becoming gangrenous, amputation is prevented. This procedure usually takes 90 minutes and ideally is performed as an outpatient procedure due to its cost benefits. Timely referral for an angiogram and intervention reduces the probability of an amputation by 90 percent.[6]

The cost of unnecessary amputations is a financial burden on our health care system, at a more than $10 billion annual cost.[7] The low rate of return to work following amputation places a burden on our workforce. If the ripple effect of each amputation on family members and communities is considered, there is an extraordinary financial burden to our economy as well.

CMS must consider the ramifications of significant cuts to revascularization services, which could likely result in more unnecessary amputations. We therefore urge CMS not to finalize the proposed clinical labor pricing inputs and to urge Congress to provide a positive update to the Medicare conversion factor in 2022 and all future years.

CLOSING THE HEALTH EQUITY GAP IN CMS CLINICIAN QUALITY PROGRAMS

ABC thanks CMS for its request for information on how to make reporting of health disparities based on social risk factors, race, and ethnicity more comprehensive and actionable for hospitals, providers, and patients. **The importance and complexity associated with the collection of better demographic data that will allow for stratification of measures and addressing gaps in health equity is worthy of a separate RFI that builds on the important questions that have been preliminarily raised in this proposed rule.**

[5] Allison, MA, Ho, E, Denenberg, JO, Langer, RD, Newman, AB, Fabsitz, RR, Criqui, MH. Ethnic-specific prevalence of peripheral arterial disease in the United States. Am J Prev Med. 2007;32:328–333.
[6] CardioVascular Coalition https://cardiovascularcoalition.com/cardiovascular-care/peripheral-vascular-intervention-amputation-prevention/
[7] Yost, M. Cost-Benefit Analysis of Critical Limb Ischemia in the Era of the Affordable Care Act. Endovascular Today, May 2014.

New and Revised MIPS Improvement Activities

ABC supports using MIPS to help to bridge the health equity gap, and, in this respect, we support the proposed new and revised MIPS health equity improvement activities, and specifically the proposed activity "create and implement an anti-racism plan," which emphasizes systemic racism is the root cause for differences in health outcomes between socially defined racial groups. We agree.

Everyday racism, in work or in health care, results in higher rates of coronary heart disease, diabetes, stroke and end-stage renal disease. Higher levels of stress and consequent fight-or-flight hormone activation leads to high blood pressure, lack of sleep, improper diet, mental strain and medical mistrust. Those living in poorer communities also experience reduced access to care, lack of available nutritious food, unsafe built environments and a propensity to more maladaptive, addictive behaviors such as smoking, alcoholism and medical noncompliance. The result is lower life expectancy, poorer quality of life and fewer years of productive life.

Complex Patient Bonus

The ABC concurs with the recommendation of the American Medical Association (AMA) that CMS should not finalize its proposal to limit the complex patient bonus to clinicians who have a median or higher value for one or both of the two risk indicators. We agree with the AMA that if clinicians who are just below the median are discouraged from treating complex patients, access to care for those patients could be reduced, leading to greater disparities and inequities in health outcomes. Per the AMA's recommendations, CMS should: standardize the risk indicators using more robust measures of central tendency and variation, such as the median and the median absolute deviation or the median positive deviation (i.e., the median absolute difference between the overall median and the actual values, either for all values or all values greater than the median); increase the cap on the Complex Patient Bonus to at least 20 points; and scale the formula so that individual clinicians in the upper quintile can receive at least a 15-point Complex Patient Bonus.

Request for Information

CMS is seeking public comment on two potential future expansions of the CMS Disparity Methods, including: (1) future potential stratification of quality measure results (by condition/procedure-specific readmission measures) by race and ethnicity, and (2) improving demographic data collection. ABC offers its perspectives generally on these subjects.

Bias in Clinical Algorithms

Closing the gap in health equity requires addressing racial bias in clinical decision making. Health care technology has advanced to incorporate evidence-based medicine and health data into algorithms that support clinical decision making through artificial intelligence (AI).

Clinical algorithms are critical to population health management.[8] Algorithms and risk prediction models should enable physicians and health systems to anticipate health care needs and allocate resources to improve outcomes for at-risk patients. At the same time, it is essential these algorithms perform equitably. As digital technology becomes more integrated into clinical care, the algorithms will be used more frequently and autonomously to guide patient care. If the data fueling the algorithms are flawed, the output will likewise be flawed as will the resultant patient care. Current health care data reflects underlying disparities. Populations facing socioeconomic barriers to accessing care are underrepresented or misrepresented in our systems. Likewise, current care patterns reflect the biases inherent to the systems collecting the data. Data enables analytics and AI, but we must understand the shortcomings of our data and the social implications of using biased data to drive care decisions. Marginalized populations not included in the data will not reap the full benefits of AI.

The ABC is aligned with the assessment that race has been misinterpreted and misused in clinical care algorithms with consequent harm to communities of color. Much of the misuse may be unintentional and based on the inclusion of faulty data reflecting current inequities into algorithm programming. However, the topic of racism in health care is more deeply rooted and complicated than clinical algorithms alone. Not addressing the inaccurate outputs from clinical algorithms incorrectly programmed to factor race and ethnicity data will lead to perpetuation of disparate care with respect to referral for treatment, allocation of resources and patient satisfaction which may ultimately lead to further disenfranchisement from the health care system through missed treatment opportunities, unfavorable outcomes and failure of treatment adherence.

Across virtually every type of diagnostic and treatment intervention, blacks and other minorities receive fewer procedures and poorer quality medical care than whites with similar disease burdens. Although the incentives to use AI algorithms for clinical decision support have worked well for acute care, chronic disease management using AI powered tools (population health management) is fraught with more complexity due to the environmental and social context that are part of patients 'lives. In fact, some clinical algorithms for heart failure management artificially raised the risk score for non-blacks which consequently reduced the 'perceived ' severity of blacks resulting in their delayed referral for advanced care.[9] Clinical algorithms are also subject to the inherent implicit biases of the clinicians using them. Research continues to document the persistence of higher implicit bias scores among physicians being associated with biased treatment recommendations and poorer communication in the care of black patients.[10,11] The role of health care providers is to provide context for the algorithm-generated decision during the clinical encounter.

Algorithms learn from historical patterns to make predictions and decisions, but if they learn from biased data they will produce biased outputs. By using biased insights to inform care

[8] Obermeyer Z, Powers B, Vogeli C, Mullainathan S. Algorithmic Bias In Health Care: A Path Forward; Nov. 1, 2019. https://www.healthaffairs.org/do/10.1377/hblog20191031.373615/full/
[9] Vyas D., et al. (2020) Hidden in Plain Sight-reconsidering the use of race correction in clinical algorithms. NEJM doi: 10.1056/NEJMms2004740
[10] Williams, D. R., Lawrence, J. A., & Davis, B. A. (2019). Racism and Health: Evidence and Needed Research. Annual review of public health, 40, 105–125. https://doi.org/10.1146/annurev-publhealth-040218-043750
[11] Breathett K, Yee E, Pool N, et al. Does Race Influence Decision Making for Advanced Heart Failure Therapies? *Journal of the American Heart Association*. 2019;8. https://doi.org/10.1161/JAHA.119.013592

decisions, systems may unintentionally create or perpetuate inequities. For example, one emerging application of AI is predicting intensive care unit (ICU) demand. Algorithms can be used to identify which inpatients are at risk for clinical deterioration and will require a transfer to an ICU. A model could be built using historical health records of patients who were transferred to ICUs. However, if the training data contains more white than black patients, the model will make better predictions for white patients. Deterioration might be underestimated for black patients, leading to fewer transfers and worse outcomes.

Data from clinical research is used to create the evidence-based guidelines that power AI engines. If incomplete, inaccurate or data skewed by underlying disparities in clinical trial access are used, then the resultant algorithm outputs will also be skewed. Clinical research is also closely tied to existing clinical guidelines. The inequities programmed into clinical guidelines also appear as inclusion/exclusion criteria which can broaden the data gap by excluding participation of minority patients.

Patients and communities should work to establish partnerships with health care and other entities using AI to provide decision support. Partnership examples include public health departments, nursing homes, local care agencies (home health, mental health), school districts, faith-based organizations, public safety providers, and other non-profit service groups (food banks). Data obtained through health information exchanges from these sources will provide more accurate representation of vulnerable populations which will improve decision making and proactive intervention algorithm accuracy. Community groups should provide feedback that can be used to validate and refine algorithms based on local users 'specific data, as opposed to the large national databases on which algorithms are typically built. Patients and communities should be a part of the local health care organization's clinical decision support tool validation and feedback mechanism. This is particularly important if an algorithm is being used across multiple care sites with different demographic profiles.

Data Collection

Patient health is heavily influenced by social determinants of health (SODH). Algorithms are often biased because non-clinical factors are not included in their programming. Algorithm accuracy has been improved by incorporating SDOH data. An example from University of North Carolina (UNC) Health System demonstrates how quickly identifying and addressing risks can significantly improve patient outcomes. As part of UNC's population health program, nursing staff would check in with patients at risk of readmission. Due to resource constraints, the staff needed to evaluate how to best focus their efforts on their most high-risk patients. The initial model used length of stay, acuity, co-morbidities, and emergency department visits. UNC partnered with a health analytics firm to build a better model for predicting readmissions. The new "Modern Social Determinants of Health" model did not begin from preconceived theories, but instead used machine learning to ingest and evaluate UNC's data to generate dramatically better predictions of readmission risk. The resulting model takes risk factors into account that are not always intuitive, and it segments the population in ways that are not medically or socially obvious. Despite the "black box" effect, the results were impressive. When compared to more traditional discharge planning rules, the new model correctly predicted twice as many readmissions when 20 percent of the population was targeted for follow-up.

The lack of diversity in data is a long-standing problem the ABC is working to address with the Cardiovascular Implementation Study (CVIS), a practice-based research registry that is integrating social determinants and technology innovation to address health disparities. CVIS is enrolling diverse patients with prioritized health conditions from collaborating ABC member practices, as well as patients from academic health centers and Federally Qualified Health Centers. CVIS prospectively collects socio-demographic and economic data at the point of care. CVIS will evaluate the safety and clinical outcomes of new therapeutic agents, including post-marketing surveillance. CVIS data collection tracks quality of care standards established by CMS and commercial health plans. Long term, CVIS will become the most comprehensive patient registry for diverse patients with cardiovascular disease and co-morbid conditions by providing real-world data to address health disparities. CVIS will inform cardiovascular algorithms and guide future research that is relevant to diverse populations.

Improvements to the collection of demographic data is challenged by traditional lack of collaboration, incompatible technology (interoperability), inadequate resourcing, and a lack of knowledge/standardization. Further, electronic health record (EHR) systems and processes are not built to collect holistic patient data. EHRs were built to be billing tools first and clinical tools second. They are often missing data and are not set up to easily capture demographic and SDOH data.

ABC Recommended Strategies

- Refine algorithms with more data, including SDOH, which can help correct for bias. The ABC CVIS registry uses the National Institutes of Health-developed PhenX Toolkit on social determinants of health to systematically collect sociodemographic data at the point of care. Collection of SDOH measures upstream factors that shape behaviors and health outcomes. PhenX provides a common currency for studying SDOH across public health research studies while allowing researchers to examine the role of SDOH and the factors related to health inequities to identify effective interventions to reduce health disparities. Such standardization of SDOH will allow the CVIS registry to expand its data capacity and predictive modeling by linking with other public health databases. Such analyses will ensure ongoing race, ethnicity and SDOH testing of clinical algorithms.

- “Train” algorithms to predict less biased outcomes and encourage algorithm developers to work with physicians and others closely involved in care delivery to build advanced prediction algorithms. If AI does not code for unintended bias in the development stage, algorithms will perpetuate bias. Bias in, bias out. AI manufacturers and researchers could be required to conduct audits of their predictions before their products ever support a patient. Rigorous validation should assess completeness and quality of data to adequately reflect the community, test relationships between variables, stratify performance results from all angles to identify disparities, and establish a strategy for ongoing performance management.

- Remove registry data collection factors that lead to generalizability of patient outcomes, the consequences of which are profound, including risk prediction scores that misrepresent risk in patients who are excluded.

- Ensure health care costs are not used as a proxy measure for health needs. Algorithms commonly used by health systems and insurance companies, which often use health care expenditures as endpoints, perpetuate existing racial biases. Lower health care costs among underserved and minority populations can be reflective of under-utilization due to access limitations and other factors, including historic medical mistrust by the African American community. The focus of AI algorithms should be on growth over savings.

- Promote partnerships with universities, research centers, agencies and professional organizations to fill data gaps using agile test-and-learn techniques across multiple AI technologies. This will also help assure specialists versed in disparities and health equity are involved in planning, integration and implementation of AI systems. Re-skilling the workforce to integrate AI into workplace processes with an eye toward diversity is a necessity.

ABC is encouraged by the evidence review being undertaken by the Agency for Healthcare Quality and Research Agency for Healthcare Quality and Research (AHRQ) on commonly used algorithms, including whether race/ethnicity is included as an explicit variable, and how algorithms have been developed and validated.

We believe stratification of quality measure results by race and ethnicity is premature. However, ABC looks forward to continuing the dialogue with CMS on advancing the data used to identify health care inequities and how payment programs and policies can be leveraged to close the health equity gap. Questions and requests for additional information should be directed to ABC policy consultant Camille Bonta at cbonta@summithealthconsulting.com or (202) 320-3658.

Sincerely,

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SGIM
Society of General Internal Medicine
Creating Value for Patients

September 13, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

SUBMITTED ELECTRONICALLY VIA http://www.regulations.gov

Re: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements

Dear Administrator Brooks-LaSure:

The Society of General Internal Medicine (SGIM) appreciate the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) proposed rule for calendar year (CY) 2022 Medicare Physician Fee Schedule (MPFS). SGIM is a member-based medical association of more than 3,300 of the world's leading academic general internists, who are dedicated to improving the access to care for all populations, eliminating health care disparities, and enhancing medical education. Our members are committed to ensuring patients have equitable and affordable access to the highest quality of care possible. As such, we look forward to commenting on the following section of the proposed rule:

- Practice Expense Clinical Labor Pricing Update
- Comment Solicitation for Codes involving Innovative Technology
- Telehealth Services
- Principal Care Management and Chronic Care Management
- Split (or Shared) Evaluation and Management Visits
- Payment for the Services of Teaching Physicians
- MIPS Value Pathways
- Health Equity Improvement Activities
- Future Potential Stratification of Quality Measures by Race and Ethnicity
- Improving Demographic Data Collection
- Health Equity Measures in MVPs
- Complex Patient Bonus

Practice Expense Clinical Labor Pricing Update

CMS is proposing to update the clinical labor inputs using the most current Bureau of Labor Statistics data in CY 2022 in conjunction with the final year of the supply and equipment pricing update. SGIM supports this proposal particularly since the current inputs are based on data from

2002 and believes the agency should always develop reimbursement policies, and specific payment rates, using the best available data. This action is long overdue; however, ***SGIM recommends that CMS phase in this update over a four-year period as was done for the supply and equipment update to minimize the reimbursement reductions to specific services in CY 2022.*** These decreases coupled with the conversion factor cut of 3.75 percent could be detrimental to Medicare beneficiary access to services as providers across the country are still struggling to address the COVID-19 pandemic and related disruptions. SGIM recognizes that CMS cannot prevent or minimize the 3.75 percent conversion factor cut in a budget neutral system, and therefore, urges the agency to act where it does have the authority as it does with this proposed update. ***Additionally, CMS should develop processes to ensure that a more regular review of inputs occurs both to improve the accuracy of Medicare payments, but also to avoid the significant decreases resulting from this proposal.***

Comment Solicitation for Codes involving Innovative Technology

CMS recognizes rapid advances in innovative technology are having a profound effect on health care delivery and is soliciting public comment to better understand the resource costs for services involving the use of innovative technologies, including but not limited to software algorithms and artificial intelligence (AI). The agency is particularly interested in how software can help to address health equities. ***SGIM thanks CMS for looking to use innovative technologies as a tool to address health inequities and agrees these technologies have an important role to play.*** However, software costs and maintenance can burden large and small practices financially and are a roadblock to more widespread adoption. ***We welcome the opportunity to work with CMS to determine how technologies, including software and AI, can be developed to in a cost-efficient manner and be deployed to improve access, patient engagement, patient safety, and self-care.***

Telehealth Services

SGIM commends CMS for implementing telehealth flexibilities within its emergency authority to ensure patients have maintained access to medically necessary care during the COVID-19 pandemic. Our members have adjusted their practices to utilize these flexibilities and believe Medicare should continue to support virtual care post-pandemic as its statutory authority allows. Therefore, we are pleased CMS is proposing to expand access to certain telehealth services based on the authority Congress provided in the Consolidated Appropriations Act, 2021 (P.L. 116-260) and respectfully request the agency consider our additional recommendations.

Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis

During the COVID-19 pandemic, CMS established Category 3 telehealth services which includes services added on a temporary basis during the public health emergency. CMS is now proposing to revise the timeframe for services added to the telehealth list under Category 3 and allow them to remain until the end of CY 2023***. SGIM strongly supports this extended timeframe.*** We believe the additional time will provide for the collection of additional telehealth utilization data which will allow for stakeholders and the agency to make evidence-based decisions when

recommending and considering these services for permanent addition to the telehealth list. ***SGIM supports all efforts to develop and implement evidence-based policy.***

During the public health emergency, the agency added a number of services to the telehealth list on an interim basis, but not on a Category 3 basis; these services will be removed when the public health emergency expires. These services include hospital inpatient services (CPT codes 99221-3), observation care services (CPT codes 99218-20, 99234-6), and telephone visit services (CPT codes 99441-3). The telephone evaluation and management (E/M) services have been an important tool for our members to deliver needed care to Medicare beneficiaries during the pandemic and we believe they will continue to improve access and adherence for patients with chronic conditions after the public health emergency concludes. SGIM recognizes that Congress must act to provide CMS with the statutory authority to continue to cover audio-only services for care outside of furnishing services for mental health conditions. In the proposed rule, CMS explained that the services most commonly billed with the audio-only modality were mental health services. ***SGIM respectfully requests the agency share with the public the audio-only utilization data that has been collected during the public health emergency to provide stakeholders with a better understanding of how these services have been utilized outside of the treatment of mental health conditions.***

Expanded Access to Mental Health Medicare Telehealth Services

CMS is proposing to eliminate the originating site and geographic restrictions for mental health services based on the authority provided in the Consolidated Appropriations Act of 2021. Given the shortage of mental health professionals and limited broadband access in some areas, the agency will allow mental health services to be delivered to established patients using the audio-only modality when the originating site is their home, despite the agency's program integrity concerns in an instance where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology. SGIM will continue to advocate that Congress eliminate the originating site and geographic restrictions more broadly and provide the agency with the statutory authority to continue covering audio-only services in appropriate circumstances.

The ability to delivery audio-only services is important for the patients our members treat who lack access to technology required for video visits. During the COVID-19 pandemic, many of our patients were not able to master audio-visual platforms due to a range of factors beyond patient or physician control such as a lack of broadband, a smartphone, or an ability to understand the technology needed for visual connection with a clinician. Audio-only visits protect vulnerable patients with chronic conditions, who may not have access to the internet, or whose internet does not support video.

Through audio-only visits, our physicians have successfully managed various chronic diseases, including diabetes and hypertension, particularly when patients are equipped with the home monitoring tools needed to monitor their numbers. However, SGIM is concerned that CMS' definition of home as it is applied here may be too limited as many patients may not have a

home in the traditional sense and experience housing insecurity which could potentially disqualify them from receiving necessary medical care. ***We respectfully request CMS provide its definition of the home in the final rule and ensure it does not perpetuate existing inequities.*** SGIM is concerned that verifying a patient is in their "home" could pose challenges/additional burden for physicians.

Other Non-Face-to-Face Services Involving Communications Technology under the PFS Expiration of PHE Flexibilities for Direct Supervision Requirements

CMS is soliciting information on whether the public health emergency-related flexibilities related to direct supervision should be made permanent. Specifically, the agency seeks comment on the extent to which the flexibility to meet the immediate availability requirement for direct supervision through the use of real-time, audio/video technology is being used during the public health emergency, and whether physicians and practitioners anticipate relying on this flexibility after the public health emergency concludes. ***SGIM believes these services have been valuable for our members during the pandemic, particularly when physicians were assigned to work off-site to reduce crowding in the clinic, and recommend they continue following the conclusion of the public health emergency.*** As an example, this flexibility helps to facilitate care when a teaching physician can only provide care from home given childcare, eldercare, or other personal constraints. By better enabling providers to provide care from where they are, patients will be better able to receive care where they are. We believe this flexibility is another important tool to expand access to care, particularly in shortage specialties like general internal medicine.

Once the public health emergency concludes, remote supervision will continue to sustain clinical capacity and support equity, as many teaching sites deliver care to vulnerable populations. Our members, many of whom serve as the primary internal medicine faculty of every medical school and major teaching hospital in the United States, have found that teaching models continue to evolve and incorporate remote supervision into practice. We believe the following is absolutely necessary for remote supervision to support robust patient care safety and quality standards: 1) adequate telecommunications technology access, 2) presence at clinic of an on-site teaching physician for in-person supervision as needed for any in-person resident clinic visits, and 3) appropriate training and practice standards for resident and teaching physicians on the scope of telemedicine practice.

Virtual Check-in

In the CY 2021 MPFS final rule, CMS adopted a longer virtual check-in – HCPCS code G2252 – on a temporary basis. In this proposed rule, the agency is proposing to permanently adopt this code and payment, based on the support it has received from stakeholders. ***SGIM supports the agency's proposal to permanently adopt this case, as it recognizes the time spent by providers delivering chronic care management. However, SGIM does not believe these check-ins eliminate the need for continued coverage of audio-only E/M services, and as mentioned, we will continue to advocate for their continued coverage.***

Principal Care Management and Chronic Care Management
The American Medical Association RVS Update Committee (RUC) recently resurveyed the Chronic Care Management (CCM) code family, including Complex Chronic Care Management (CCCM) and Principal Care Management (PCM), and added five new CPT codes 99X21, 99X22, 99X23, 99X24, and 99X25. In this proposed rule, the agency is proposing to adopt the work and PE values as recommended by the RUC. ***SGIM supports CMS' proposal to adopt the RUC recommended values, as these services are commonly billed among our members and allow us to manage the complex care patients require and improve patients' outcomes.***

Split (or Shared) Evaluation and Management Visits
CMS is proposing changes to its split (or shared) E/M visit policy. Specifically, the agency is redefining its rules when these services are delivered in the facility setting where the "incident to" billing rules do not apply, limiting the billing practitioner to either the physician or non-physician provider (NPP) who provides more than half of the patient visit as indicated by time. SGIM would like to commend CMS for supporting and working to promote team-based care. While we understand the agency is attempting to distinguish between split (or shared) visits and services furnished incident to the professional services of a physician, SGIM is concerned that this may become burdensome for physicians and NPPs who will be forced to become clock watchers to determine which practitioner performed the majority of the visit. Under the new E/M documentation guidelines, it is more common to select visit level by medical decision-making (MDM) rather than time, so this proposal represents a significant disruption to usual practice patterns***. We respectfully request CMS reconsider this policy and develop an alternate that does not increase burden on providers and recognizes typical practice patterns in medicine.***

Payment for the Services of Teaching Physicians
SGIM recognizes that CMS is not proposing to make changes to the services residents can deliver under the primary care exception. Outside of the COVID-19 public health emergency, certain lower and mid-level office/outpatient E/M services provided in certain primary care centers are exempt from the physical presence requirement under the primary care exception. However, to address the COVID-19 pandemic, the agency expanded the list of services on a temporary basis. This expansion included all levels of an office/outpatient E/M service (CPT codes 99202-99205 and 99211-99215) provided in primary care centers may be provided under direct supervision of the teaching physician by interactive telecommunications technology. SGIM has found this flexibility important in managing the care of many chronically ill Medicare beneficiaries. ***As such, SGIM requests that the agency permanently expands the services that can be provided under the primary care exception using virtual supervision to CPT codes 99214 and 99215.*** The pandemic has highlighted the need for resident physicians to be available to provide primary care, and due to pandemic-related social distancing restrictions, it is almost impossible to provide direct, in-person supervision for all resident encounters.

MIPS Value Pathways in MVPs
CMS is continuing to move forward with the development of MIPS Value Pathways (MVPs) but is proposing to delay the transition to MVPs to the CY 2023 performance year due to the COVID-19

pandemic. ***SGIM supports this decision and believes CMS should finalize this proposal.*** Given the challenges continuing to be posed by the COVID-19 pandemic, a January 1, 2022 start date would provide unnecessary burden for providers.

Additionally, SGIM supports CMS' focus on the development and implementation of MVPs, a framework linking measures and activities across the four MIPS performance categories to create a more coherent program. Many SGIM members treat vulnerable patients at safety net institutions, and therefore, we support the steps the agency is taking to do a better job facilitating the collection of more meaningful and comparable performance data using fewer, but more relevant, measures while minimizing measure selection bias. We ultimately believe this will better enable providers and CMS to improve the quality of care delivered to patients. Further, we support the implementation of MVPs that will allow providers to be measured against others delivering similar types of care to similar patient populations.
However, SGIM does have significant concerns about CMS' proposal to sunset traditional MIPS at the end of the CY 2027 performance period and require mandatory MVP reporting in the CY 2028 performance period and subsequent years. ***SGIM urges CMS to delay the phase-out of traditional MIPS or at least not set a date certain for its elimination until more MVPs have been developed and the agency and stakeholders have a better understanding of the timeline for the development and deployment of new MVPs.***

Health Equity Improvement Activities

SGIM appreciates the new and modified MIPS improvement activities under the Achieving Health Equity subcategory. SGIM commends CMS on the Anti-Racism Plan and Food Insecurity Identification and Treatment improvement activities. ***However, SGIM recommends that all health equity subcategory Improvement Activities receive high weighting to emphasize CMS' commitment to achieving health equity and to incentivize behavior change.***

Future Potential Stratification of Quality Measure Results by Race and Ethnicity

SGIM appreciates CMS' desire to identify care gaps in vulnerable populations, such as traditionally marginalized racial and ethnic groups. However, SGIM strongly cautions against focusing on race and ethnicity alone, as race and ethnicity are not the social determinants of health (SDOH) which are the direct primary mediators of inequities and poor health outcomes. As an example, a New England Journal of Medicine article cites a large cohort study in Louisiana, in which *"76.9% of the patients who were hospitalized with Covid-19 and 70.6% of those who died were black, whereas blacks comprise only 31% of the Ochsner Health population. Black race was not associated with higher in-hospital mortality than white race, after adjustment for differences in sociodemographic and clinical characteristics on admission*[1]*."* The assignment of race is historically based on social constructs, and decades of oppressive policies regarding these social constructs and interpretations of race have dictated the resources allocated to these

[1] Price-Haywood EG, Burton J, Fort D, Seoane L. Hospitalization and Mortality among Black Patients and White Patients with Covid-19. N Engl J Med. 2020 Jun 25;382(26):2534-2543. doi: 10.1056/NEJMsa2011686. Epub 2020 May 27. PMID: 32459916; PMCID: PMC7269015.

groups. For these reasons and others, SGIM believes that census-tract level indices of community social vulnerability are the best way to currently assess social risk.

Furthermore, to truly close the health equity gap, SGIM recommends that CMS not only stratify existing clinical quality measures by social risk but also support the creation of health equity measures that specifically evaluate the care being provided to address SDOH for at-risk populations. Collecting SDOH data should first and foremost be for the purpose of screening the health-related needs of patients (e.g., housing insecurity, food insecurity) so that they can be addressed. Drawing from the Accountable Health Communities Model, SGIM believes that equity measures must be developed to evaluate aspects of health care delivery, such as:

- Demonstration of language-concordant care delivery at levels that match the language proficiency of the communities served;
- Appropriate screening for social needs (e.g., food and housing insecurity), referrals for social services, use of navigators, and the degree to which those referrals are acted upon and completed, with the loop being closed;
- Participation in Community Health Needs Assessments;
- Degree to which needs assessment findings are acted upon;
- Level of investment in social services; and
- Level of community partnerships, including collaboration with county health departments and the state departments of health.

Improving Demographic Data Collection

Building on the Agency for Healthcare Research and Quality's framework for addressing health equity, SGIM supports CMS' efforts to describe disparities in health outcomes using more nuanced social risk data. We support using and developing methodologies that link Medicare administrative data to census-tract data.

We agree with a standard approach to assessing SDOH that is conducted across all health systems that care for Medicare and Medicaid beneficiaries. We also agree that the collection of structured, robust, individual-level SDOH data has the potential to help describe health-related unmet needs in the Medicare population. ***SGIM recommends CMS invest in the development of a nationwide SDOH tool to capture this relevant data on a regular basis, in line with the current standards of determining beneficiary access. However, we also caution that the collection of socioeconomic data at a more individual patient level can be a sensitive topic, open to potential abuse, and may retraumatize patients already affected by bias, barriers and structural racism***. Furthermore, training of clinic and health system staff to collect this information in a sensitive and robust way is time- and resource-intensive. Mandating practices to collect this data without adequate support and training in well-established frameworks, alongside fully engaged and empowered community partners, can have unintended consequences. Possible unintended consequences include inaccurate data collection (e.g., assigned rather than self-reported race/ethnicity/gender), patient mistrust (particularly among individuals historically traumatized by the healthcare system), psychological harm, and moral injury to providers, who feel they have "nothing to offer" their patients.

Notwithstanding these issues, when social and demographic data are captured for individual care through trusted and trained healthcare teams empowered with community resources and partnerships to address social determinants, this data may serve as a powerful tool to combat existing health inequities at their source. It is our expert opinion that significant resources are required to develop frameworks for structured systems to collect, maintain, and utilize these socioeconomic data in trusted, caring, and sensitive ways. In our experiences, it is likely that the persons tasked with collecting such sensitive information are those who share longitudinal and trusted relationships with patients, perhaps in the form of patient navigators, community health workers, and nurse care coordinators who "follow" patients across the healthcare continuum (e.g., across inpatient and outpatient settings and health systems). ***SGIM believes such frameworks must be created to build health equity-focused value metrics in the inpatient, outpatient and post-acute settings, and across transitions of care.***

Health Equity Measures in MVPs – Request for Information

SGIM commends CMS on their commitment to prioritize the development of health equity measures in future cycles of measure development. SGIM agrees that health equity measures should be included in the foundational layer of all MVPs as a required component. Developing health equity measures will clearly be a multistakeholder collaboration. Many examples do already exist, ranging from state Medicaid programs to the Accountable Health Communities model. ***As stated above in the health equity RFI section, SGIM believes that measures explicitly addressing social determinants of health, such as food and housing insecurity, must be developed, as well as measures evaluating engagement with appropriate community partners.*** SGIM welcomes the opportunity to engage with CMS leadership on this in the future.

Complex Patient Bonus

SGIM appreciates CMS' incorporation of recent studies[2] into the complex patient bonus calculation and the detailed description of its own evaluation. CMS' ongoing efforts to improve equity by increasing the support to the providers caring for the most complex patients, specifically those at highest social risk, have proven to be invaluable for our members. In the short term, SGIM agrees with the changes proposed by CMS to continue the increased complex patient bonus with a value up to 10 points, as well as the methodologic changes to apply the bonus only to the providers/practices with social or medical complexity scores above the median. However, we continue to advocate for additional changes in CMS' approach to account for social risk to achieve CMS' two stated goals – protecting access to care for socially complex patients and placing providers who care for socially complex patients at a disadvantage. We believe dual eligible status continues to be an incomplete proxy measure for social risk. Using dual eligible status as the only marker for social complexity under-captures social risk for some populations, such as the working poor, and most notably, those in non-Medicaid expansion

[2] Johnston KJ, Hockenberry JM et al (Sept 2020) "Clinicians With High Socially At-Risk Caseloads Received
Reduced Merit-Based Incentive Payment System Scores" HEALTH AFFAIRS 39, NO. 9 (2020): 1504–1512.

states. Most of these states are in the South, where a higher share of the Black population resides[3], thereby perpetuating structural racism in health care.

Further, neighborhood indices which evaluate the social vulnerability of the communities which providers serve based on census-tract data are widely accepted as better measures of social risk, do not require additional data to be captured by the providers/practice, and have been used in various studies of Medicare payment models.[4567] Many such composite measures of social determinants of health exist, including the Social Vulnerability Index, the Area Deprivation Index, the Community Needs Index, and the Distressed Communities Index. ***SGIM recommends that CMS explore the use of such indices as the basis for fairly evaluating social risk and adjusting value-based payments.***

SGIM believes that having a combined complex patient bonus accounting for clinical complexity and social complexity together reduce the emphasis on equity that has become a central focus of the Biden Administration. Social determinants of health are the major driver of health care inequities, and thus ***SGIM recommends that CMS make explicit the importance of accounting for social risk by creating a separate measure, as SGIM has previously suggested.***

While the complex patient bonus offers potential to level the playing field, identifying the appropriate magnitude of bonus remains challenging, as evidenced by the Johnston et al paper, as well as CMS' request for comments on the appropriate multiplier and cap for the complex patient bonus for 2022. Peer grouping practices (as per the Hospital Readmissions Reduction Program) according to social complexity would mitigate this concern until the appropriate magnitude of the complex patient bonus can be identified. ***As such, SGIM recommends peer grouping based on social complexity to ensure providers and practices caring for the most socially vulnerable patients are not unfairly penalized.***

In the long-term SGIM continues to recommend stronger action to support practices caring for the most complex patients, especially socially complex patients. CMS states the intent of this complex patient bonus to be temporary. While clinical risk adjustment methodology continues to be refined at a detailed level, there continues to be no other accounting for social risk within MIPS or MVPs besides this bonus. As addressed in more detail above, heath equity measures

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[3] https://www.kff.org/racial-equity-and-health-policy/issue-brief/health-coverage-by-race-and-ethnicity/

[4] Zhang Y, Li J, Yu J, Braun RT, Casalino LP. Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. JAMA Netw Open. 2021 Jun 1;4(6):e2113212. doi: 10.1001/jamanetworkopen.2021.13212. PMID: 34110394; PMCID: PMC8193453.

[5] Ash, A. S., et al. (2017). "Social Determinants of Health in Managed Care Payment Formulas." JAMA Intern Med 177(10): 1424-1430

[6] Joynt Maddox KE, Reidhead M, Hu J, Kind AJH, Zaslavsky AM, Nagasako EM, Nerenz DR. Adjusting for social risk factors impacts performance and penalties in the hospital readmissions reduction program. Health Serv Res. 2019 Apr;54(2):327-336. doi: 10.1111/1475-6773.13133. PMID: 30848491; PMCID: PMC6407348.

[7] Hu J, Kind AJH, Nerenz D. Area deprivation index predicts re-admission risk at an Urban Teaching Hospital. Am J Med Qual. 2018;33(5):493-501.

must be developed. In the meantime, a strong complex patient bonus (or peer grouping based on social risk) remains a critical tool to promote equity in MIPS to ensure that safety net providers/practices supporting the most socially complex Medicare beneficiaries are not financially penalized due to inadequate accounting for social determinants of health.

Thank you again for the opportunity to provide comments on the MPFS. We look forward to continuing to work with CMS and welcome the opportunity to discuss these issues with you further. Should you have any questions, please do not hesitate to contact Erika Miller at emiller@dc-crd.com.

Sincerely,

Monica L. Lypson, MD, MHPE
President, Society of General Internal Medicine

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TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

September 13, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1751–P
P.O. Box 8016
Baltimore, MD 21244–8016

Re: 2022 Medicare Physician Fee Schedule and Quality Payment Program Proposed Rule

Submitted via *Federal eRulemaking Portal at www.regulations.gov*

Dear Administrator Brooks-LaSure:

On behalf of the Texas Medical Association's (TMA's) more than 55,000 physician and medical student members, I write with comments on the 2022 Medicare Physician Fee Schedule and Quality Payment Program proposed rule as published by the Centers for Medicare & Medicaid Services (CMS) in the July 23, 2021, *Federal Register*.

TMA is the largest state medical society in the nation and is committed to improving the health of all Texans. TMA charters 110 county medical societies. It is the mission of TMA to stand up for Texas physicians by providing distinctive solutions to the challenges they encounter in the care of patients.

Of grave concern to Texas physicians is that the proposed rule estimates the 2022 conversion factor to be $33.5848, a 3.75% decrease from the 2021 conversion factor. The reduced conversion factor is exacerbated by already low Medicare payment for physician services. Taken along with the imminent payment cuts from the Medicare sequester and the Statutory Pay-As-You-Go Act, this cut will be financially disastrous for physician practices. TMA will call on Congress to immediately address the forecasted cut before the end of the year. Otherwise, patients may experience a reduced ability to access care as physicians are unable to sustain their practices. **CMS should work with Congress to recognize the need for critical reforms to the Medicare Physician Fee Schedule system, including addressing the budget neutrality requirement, which can lead to arbitrary reductions in payment unrelated to the increasing cost of providing care.**

Specific to the Merit-Based Incentive Payment System (MIPS), we are also concerned with the proposed changes that will create additional complexity and confusion for physicians and patients. As discussed in our detailed comments, and especially in the context of the current and ongoing public health emergency (PHE), CMS must strive to maintain existing policies to the greatest extent possible. Annual proposed changes to MIPS contribute greatly to physician regulatory compliance challenges, leading to physician burnout. **TMA pleads with the agency to tweak MIPS requirements only as needed or when doing so significantly reduces burdens physicians bore navigating the MIPS program.**

Attached to this cover letter TMA offers our detailed comments, recommendations, and suggestions to improve the Medicare program. In summary, TMA:

Texas Medical Association 401 West 15th Street Austin, Texas 78701-1680 (512) 370-1300 (800) 880-1300 Fax (512) 370-1632 www.texmed.org

- Fully supports Relative Value Scale Update Committee (RUC) recommendations to value and describe Current Procedure Terminology® (CPT®) codes and calls on CMS to fully adopt all RUC recommendations.
- Asks the agency to institute a four-year transition for new practice expense RVU wage data and to update the data more frequently to avoid disruptive impacts to the fee schedule.
- Fully agrees with CMS' proposal to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of 2023.
- Believes a physician-led and collaborative team-based approach is optimal for patient care delivery and overall health care outcomes, especially when using telehealth.
- Recommends that CMS and Congress consider paying physicians appropriately for time spent caring for patients regardless of delivery type.
- Calls on CMS to implement and pay for CPT code 99072 regarding PHE-related costs.
- Especially appreciates CMS leaving incident-to policies intact in the context of evaluation and management (E&M) split billing.
- Recommends that CMS apply the office visit E&M increases uniformly across all services and specialties and not hold specific specialties to a different standard from others.
- Urges the agency to acknowledge that scope of practice is defined by state law, not by CMS.
- Strongly supports the proposal to delay enforcement of the Appropriate Use Criteria program by at least one year until the latter of Jan. 1, 2023, or the Jan. 1 that follows the end of the public health emergency.
- Supports the proposal to freeze the quality performance standard at the 30th percentile of MIPS quality performance category scores for an additional year for the Medicare Shared Savings Program.
- Supports revisions to the vaccine exemption in the physician self-referral regulations but suggests the proposed changes to the indirect compensation arrangement definition be narrowed.
- Fully supports the proposal to postpone electronic prescribing of controlled substances compliance by another year to Jan. 1, 2023, and emphatically asks CMS not to impose penalties for noncompliance.

Regarding the proposed changes to the Quality Payment Program, in summary, TMA:

- Urges CMS to not add to the burden of MIPS requirements and pleads with the agency to tweak requirements only as needed.
- Calls on CMS to aggressively focus on the development of voluntary, physician-led alternative payment models instead of pursuing MIPS Value Pathways.
- Implores CMS to maintain the quality performance category weight at 40% of a MIPS score, especially in the context of a public health emergency.
- Opposes the cost category weight being increased to 30% and urges CMS to delay increases to it until the end of the PHE. Instead, CMS should maintain the quality performance category weight at 40% of a MIPS score.
- Cautions CMS that the cost category is administratively burdensome to many physicians, and building further complexities into this category exacerbates the burden.
- Urges CMS not to penalize physicians who report on a suspended improvement activity and asks CMS to modify and remove improvement activities only when absolutely necessary.
- Supports and appreciates CMS' proposal to maintain the Query of PDMP measure as optional and worth 10 bonus points in the MIPS promoting interoperability category.
- Strongly opposes CMS' proposal that physicians be required to make patient health information available indefinitely starting with encounters on or after Jan. 1, 2016, since the tools to do so are unavailable and the proposed requirement is absolutely premature. Instead, TMA strongly encourages CMS to fully align with 21st Century Cures Act date and data requirements.

- Recommends that CMS make the SAFER Guides attestation an optional bonus measure for conducting an annual self-assessment of the high-priority practices listed in Office of the National Coordinator for Health Information Technology's Safety Assurance Factors for EHR Resilience (SAFER) Guides.
- Fully supports and thanks CMS for the proposal not to require small practices to submit a hardship application for exemption from promoting interoperability.

Thank you for the opportunity to comment. TMA stands ready to provide you and others within the agency with our policy expertise and any additional assistance you may find useful. If you have any questions, please do not hesitate to contact Robert Bennett, TMA vice president of medical economics, at Robert.Bennett@texmed.org.

Sincerely,

E. Linda Villarreal, MD
President
Texas Medical Association

Attachment

COMMENTS OF THE TEXAS MEDICAL ASSOCIATION

Re: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post Payment Medical Review Requirements.

Practice Expense Relative Value Units

Summary

The Centers for Medicare & Medicaid Services (CMS) proposes to implement 76% of the AMA/Specialty Society RVS Update Committee (RUC) recommendations related to the physician work of performing services articulated by new and revised Current Procedure Terminology® (CPT®) 2022 codes.

The agency discusses how, in 2022, CMS will implement new wage data from the U.S. Bureau of Labor Statistics to update clinical labor costs and requests feedback on whether to fully implement the proposal or institute a four-year transition.

TMA Response

TMA fully supports RUC recommendations to value and describe CPT codes. Thus we call on CMS to fully adopt all RUC recommendations. **Since the new wage data significantly impact the fee schedule, TMA asks the agency to institute a four-year transition for changes to be realized gradually.** We also call on CMS to update these data more frequently so as not to lead to such dramatic changes.

Telehealth and Other Services Involving Communications Technology

Summary of Retention of Category 3 Services Through the End of 2023

CMS proposes to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of 2023. This allows CMS more time to collect information regarding utilization of these services during the pandemic. It also provides stakeholders the opportunity to develop support for the permanent addition of appropriate services to the list of approved telehealth services.

TMA Response

Since the public health emergency (PHE), TMA has seen rapid adoption of telehealth, and patients continue to find value in the added service when the condition is appropriate for this delivery type. TMA appreciates that CMS continues to offer telehealth flexibilities, especially as the COVID-19 delta variant continues to put all patients at risk, even those vaccinated. **TMA fully agrees with CMS' proposal to retain all services added to the Medicare telehealth services list on a Category 3 basis until the end of 2023.**

TMA recommends that CMS follow the recommendations of the national physician specialty societies representing physicians in the various specialties reflected by those services listed in Table 11, "Services Added to the Medicare Telehealth Services List for the Duration of the PHE for COVID-19 but Were not Added to the Medicare Telehealth Services List on a Category 3 Basis."

Summary of Implementation of Provisions of the Consolidated Appropriations Act of 2021

CMS proposes to amend its regulation to define "interactive telecommunications system" to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health and substance-use disorders furnished to established patients when the originating site is the patient's home. CMS is further proposing to adopt a similar, ongoing requirement that an in-person item or service must be furnished within six months of such a mental health telehealth service.

TMA Response
TMA agrees with the requirement that an in-person visit must take place within six months prior to the first time an audio visit is furnished for substance-use disorder and mental health counseling. If the visits are for counseling only, the in-person requirement may not be needed, but if medications are prescribed, an in-person visit is appropriate.

TMA urges CMS to consider expansion of audio-only visits to patients without mental health and substance-use disorders. For audio-only visits, CMS should seek public input for new, permanent, separately payable services – beyond the existing and low-paying check-in services – that can be provided appropriately through that technology and in a manner consistent with other applicable state and federal law. These new services would significantly impact rural and underserved populations as well as complex and chronically ill patients who do not have access to two-way audio-visual technology.

Regarding whether the required in-person, nontelehealth visit could be furnished by another physician of the same specialty and within the same group as the physician who furnishes the telehealth service, TMA believes it is appropriate. Further, TMA concurs with CMS that the patient may virtually see other physicians in the group who are covering for each other or if the first physician is unavailable or has left the group.

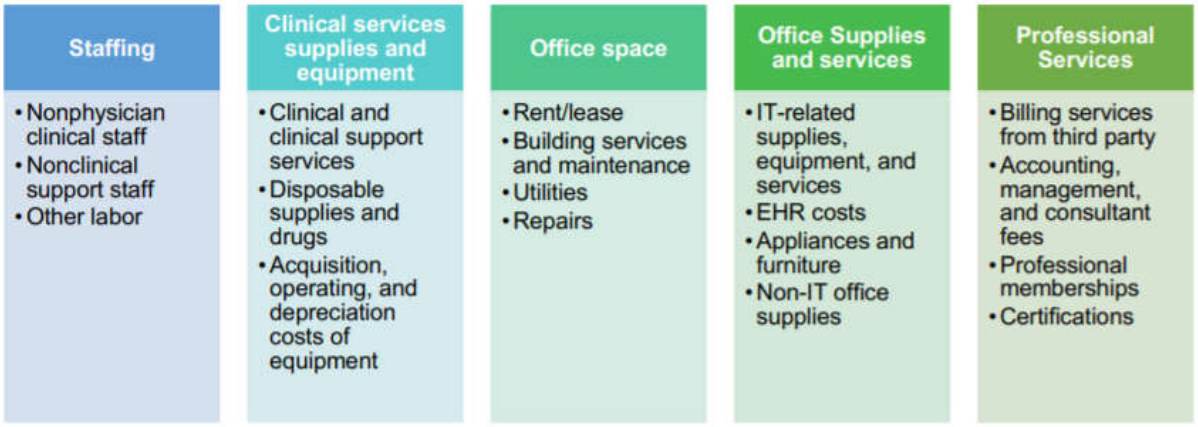
Summary of Expiration of PHE Flexibilities for Direct Supervision Requirements
During the public health emergency, CMS allowed the requirement for direct supervision to be met for diagnostic tests, physicians' services, and some hospital outpatient services through the use of virtual presence using real-time audio-video technology, instead of requiring a physician's physical presence. CMS seeks comment on whether this policy should be extended beyond the PHE, and, if so, whether it should be extended for only a subset of services and whether these services should require a service level modifier.

TMA Response
TMA believes direct supervision should revert to the pre-PHE standards that require a supervising physician's physical presence. **TMA believes a physician-led and collaborative team-based approach is optimal for patient care delivery and overall health care outcomes, especially when using telehealth.**

Summary of Payment Parity
CMS did not propose payment parity for services provided via telehealth with services provided in person.

TMA Response
TMA believes CMS and Congress should consider paying physicians appropriately for time spent caring for patients regardless of delivery type. The public health emergency widely opened the doors to telehealth, and patients and physicians alike quickly adapted. Patients will now expect telemedicine visits when they're appropriate. In fact, telemedicine really is about convenience for the patient more so than the physician.

Physicians must have the flexibility to decide whether to see their patients via telehealth or in person without unnecessary and disconnected pricing incentives. Physician payment is determined using the resource-based relative value scale, which aligns payments based on the cost and resources used to provide services using three factors: (1) physician work (54%), (2) practice expense (41%), and (3) medical liability (5%). A recent RAND study lists five practice expense categories for care delivery and some components within each one.



For continuity of care and thus better health outcomes, patients should be encouraged to seek telemedicine visits from their own physician. Augmenting a physician's practice with telemedicine incurs additional expenses different from those of delivering only in-person care. Clinical staff in the physician's practice still have integral roles in telemedicine visits by gathering the history of present illness and other visit-related information. Plus, offering telemedicine adds these expenses to a brick-and-mortar practice:

- Telemedicine software and supporting equipment (monitors, cameras, digital exam tools);
- Staff and physician telemedicine training;
- Additional staff time assisting patients with technology challenges;
- Enhanced security;
- Remote patient monitoring tools;
- Telemedicine-specific policies and procedures;
- Supplemental telemedicine patient-education materials; and
- Expanded internet bandwidth.

When physicians use their existing practice to conduct a telemedicine visit for new and established patients, they should be paid at least the same rate as for an in-person visit. **TMA's recommendation is that CMS and Congress ensure that services provided to a Medicare patient are paid according to the physician fee schedule regardless of whether the care is delivered in person or via telemedicine.**

Valuation of Specific Codes

Summary

CMS proposes valuation of multiple codes that are new or revised for 2022. This includes proposals related to use recommendations by the Relative Value Scale Update Committee for chronic care management (CCM) and principal care management (PCM) services.

CMS also seeks comments on PHE-related costs, such as disease control measures, research-related activities and services, or PHE-related preventive or therapeutic counseling services.

The agency also seeks comments on coding and payment for chronic pain management.

TMA Response

TMA strongly supports CMS' proposal to follow the RUC recommendations for CCM and PCM services.

Regarding PHE-related costs, TMA calls on CMS to implement and pay for CPT code 99072 (Additional supplies, materials, and clinical staff time over and above those usually included in an office

visit or other non-facility service[s], when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious disease) to compensate physician practices for the additional supplies and new staff activities required to provide safe patient care during the COVID-19 PHE without patient cost-sharing.

Regarding chronic pain management, TMA appreciates the agency addressing and achieving safe and effective dose reduction of opioid medications when appropriate. TMA supports improved access to substance-use disorder treatment, especially through co-location of physical health, mental health, and substance-use services and through wider availability of evidence-based medication-assisted treatments.

Evaluation and Management Visits

Summary

In this proposed rule, the agency is reviewing other evaluation and management (E&M) visit code sets and proposes clarifications regarding split (or shared) visits, critical care services, and teaching physician visits. Specifically, CMS proposes to define a split (or shared) visit as an E&M visit in the facility setting that is performed in part by both a physician and a nonphysician practitioner (NPP) who are in the same group.

The agency proposes to allow physicians and NPPs to bill for split (or shared) visits for both new and established patients, and for critical care and certain skilled nursing facility and nursing facility E&M visits.

Unfortunately, not included in the proposed regulation is a physician stakeholder recommendation calling on CMS to apply increased 2021 valuation of the office E&M visits to the visits incorporated in the surgical global packages. This request resulted from CMS implementing significant revisions to office and outpatient E&M codes in 2021, as recommended by TMA and others.

TMA Response

We are generally supportive of the proposal to define a split (or shared) visit as an E&M visit in the facility setting for which incident-to payment is not available and that is performed in part by both a physician and a nonphysician practitioner. However, we urge CMS not to require a modifier to be reported for split (or shared) visits since modifiers add a level of administrative burden that the new E&M coding structure and guidelines were designed to alleviate. We also support CMS allowing such visits for new and established patients. **We especially appreciate CMS leaving incident-to policies intact.**

TMA supports the proposal to adopt CPT guideline language for critical care services. However, we ask the agency to allow, when clinically appropriate, additional services to be furnished on the same calendar day that the critical care services are furnished.

We are concerned regarding the values of E&M office visits within global surgery codes. Medicare statute specifically prohibits CMS from paying physicians differently for the same work: "The Secretary may not vary the ... number of relative value units for a physicians' service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician."[1] Thus TMA emphatically urges CMS to apply the increased 2021 valuation of the office E&M visits to the visits incorporated in the surgical global packages. CMS' position implies that the physician work for office visits is not the same when performed in a surgical global period, which is an inaccurate assumption. **TMA recommends that CMS apply the office visit E&M increases uniformly across all services and specialties and not hold specific specialties to a different standard from others.**

[1] 42 U.S. Code §1395w-4(c)(6).

Finally, we support the proposal that counts only the time the teaching physician was present in determining the office or outpatient E&M visit level for teaching physician services.

Billing for Physician Assistant Services

Summary

Currently, Medicare pays the employer of a physician assistant (PA) and does not pay the PA directly. In this proposed rule, CMS implements a provision of the Consolidated Appropriations Act of 2021 that will allow PAs to bill Medicare for professional services provided under Medicare Part B beginning Jan. 1, 2022. As part of this, CMS notes that PAs may reassign their rights to payment for their services and may choose to incorporate as a group composed solely of practitioners in their specialty and bill the Medicare program, in the same way nurse practitioners and clinical nurse specialists may do.

TMA Response

While TMA recognizes the important role that PAs play in the health care system and we acknowledge the agency is required to implement the policy from the Consolidated Appropriations Act of 2021, TMA believes a physician-led and collaborative team-based approach is optimal for patient care delivery and overall health care outcomes. Furthermore, it remains TMA's policy that payment for services performed by a physician assistant should be made directly to the responsible physician. While greater use of nonphysician practitioners can improve the system, responsibility for care must be clearly defined if various personnel are to work together effectively to provide high-quality services for the patient. It is critical that CMS not expand scope of practice to an extent that surpasses the state licensure, education, and training of nonphysician practitioners. **As CMS contemplates ways to expand NPPs' scope of practice, it is critical for CMS to acknowledge that scope is defined by state law, not by CMS.** TMA calls on the agency to adopt policies that ensure Medicare beneficiaries continue to have access to physician services. We also call for policy that promotes patients' ability to know and understand who are providing care, what their licensure is, and what education and training they have.

Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter as Certain Colorectal Cancer Screening Tests

Summary

Colorectal cancer screening tests fall within the scope of Medicare Part B benefits and under the definition of "preventive services." The Affordable Care Act provides for payment for U.S. Preventive Services Task Force grade A or B preventive services at 100% of the lesser of the actual charge or the fee schedule amount; thus no beneficiary coinsurance is required. When a flexible sigmoidoscopy or colonoscopy is performed as a diagnostic test, the beneficiary is responsible for Part B coinsurance (normally 20%) associated with the service.

In this section, CMS is implementing a provision from the Consolidated Appropriations Act of 2021. This law establishes patient coinsurance rules for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. Effective Jan. 1, 2022, the rule expands the definition of the colorectal cancer screening test to include a "related procedure, including removal of tissue or other matter, furnished in connection with, as a result of, and in the same clinical encounter." In addition, the proposed rule establishes a phased-in increase in the Medicare payment with a decrease in the patient's coinsurance. The new payment structure will be set at 80% Medicare payment with 20% patient coinsurance gradually shifting to 100% Medicare payment and no coinsurance by 2030.

TMA Response

TMA supports coverage for colorectal cancer screening in which patients and physicians should have the option to use a variety of tests, such as a fecal occult blood test, fecal immunochemical test, stool DNA

test, flexible sigmoidoscopy, colonoscopy, double-contrast barium enema, CT colonography (virtual colonoscopy), or other appropriate techniques, in accordance with the most recently established national guidelines in consultation with interested specialty societies and scientific organizations for the ages, family histories, and frequencies referenced in these guidelines.

TMA supports the agency's proposal to change CMS' current regulations to include "colonoscopies and sigmoidoscopies that begin as screening services, but where a polyp or other growth is found and removed as part of the procedure" in the definition of colorectal screening services. The eventual elimination of coinsurance for this procedure is sound policy that will reduce the financial burden facing Medicare beneficiaries whose screenings result in a diagnostic procedure. In turn, this change will promote utilization of colorectal cancer screenings that save lives.

Vaccine Administration Services

Summary

In the proposed rule, CMS discusses that Medicare payment for vaccine administration services is increasingly insufficient. The agency seeks comments on the cost of vaccine supplies and administration and indicates it may use this information to create a new, more sustainable payment methodology for vaccine administration services under the Medicare Physician Fee Schedule.

CMS also seeks comments on whether monoclonal antibody products used to treat COVID-19 should be treated the same way as other physician-administered drugs and biologicals under Part B.

TMA Response

TMA appreciates CMS acknowledging and addressing insufficient payment for vaccine administration services, especially since our members have consistently expressed how inadequate vaccination administration payment is. Complicating the issue is the COVID-19 vaccine, given its onerous reporting, complicated storage, and specific handling requirements. Many Texas physician offices have hired new staff just to input vaccination data into ImmTrac2, the state's immunization registry, and purchased data loggers for their refrigerators/freezers to comply with the COVID-19 vaccine administrator requirements. We urge CMS to factor these expenses into new payment methodology for vaccine administration services.

TMA supports Medicare Part B coverage of monoclonal antibodies to treat the rapid rise of COVID-19 infections. Demand for monoclonal antibody therapy is increasing, and we urge CMS to pay physicians accordingly.

Appropriate Use Criteria for Advanced Diagnostic Imaging

Summary

The Appropriate Use Criteria (AUC) program requires ordering physicians to consult appropriate-use criteria using a clinical decision support mechanism prior to ordering advanced imaging services for Medicare beneficiaries, and furnishing physicians to report this information on the claim.

CMS now proposes to delay enforcement of the AUC program by at least one year until the latter of Jan. 1, 2023, or the Jan. 1 that follows the end of the public health emergency.

TMA Response

TMA strongly supports this proposal and applauds CMS for recognizing the significant challenges AUC creates, the disruptions caused by the COVID-19 pandemic, and the need for more time for an educational campaign and operations testing period.

While TMA acknowledges the importance of evidence-driven ordering, we maintain operational concerns with the AUC program that must be addressed before its enforcement. Further, the COVID-19 PHE greatly limits physician practices' ability to prepare or to participate in an educational campaign and operations testing period. Therefore, TMA strongly supports the CMS proposal to delay enforcement of the AUC program.

Medicare Shared Savings Program

Summary

Under the Medicare Shared Savings Program (MSSP), physicians and other practitioners may create accountable care organizations (ACOs), which are designed to hold participating physicians and practitioners accountable for the quality, cost, and experience of care for Medicare fee-for-service beneficiaries. MSSP has multiple tracks, including the Basic and Enhanced tracks.

In this regulation, CMS makes several proposals to the MSSP, including these proposals to:

- Freeze the quality performance standard at the 30th percentile of the Merit-Based Incentive Payment System (MIPS) quality performance category scores for an additional year;
- Add several codes to the list of primary care services, which CMS uses to attribute patients to the ACO;
- Extend the CMS Web Interface reporting option two more years;
- Ease burdens and costs of ACO repayment mechanisms by cutting in half the percentages used in the existing repayment mechanism amount calculations;
- Reduce MSSP application burden by lowering document submission requirements around prior participation and sample and executed ACO participant agreements; and
- Change beneficiary notification requirements for ACOs that select prospective assignment by only requiring notices to be sent to beneficiaries prospectively assigned to the ACO.

TMA Response

TMA fully supports the CMS proposal to freeze the quality performance standard at the 30th percentile of MIPS quality performance category scores for an additional year. During the COVID public health emergency, physicians have found it increasingly difficult to meet HEDIS quality measures.

Regarding the proposal to add new codes to the list of primary care services, we understand the need for CMS to refine the attribution process, though we urge CMS to carefully monitor primary care services to ensure they are performed predominately by primary care physicians.

We support the proposal to extend the CMS Web Interface reporting option for an additional two years.

TMA supports CMS efforts to reduce administrative burdens by simplifying documentation requirements for MSSP application and beneficiary notification requirements under the prospective assignment option. These types of administrative reductions especially benefit small ACOs led and managed by small, independent physician groups.

Medicare Provider and Supplier Enrollment Changes

Summary

With the goal of strengthening program integrity, CMS proposes several revisions to the physician and provider enrollment process. These include:

- Expanding the agency's authority to deny or revoke a physician, provider, or supplier's enrollment based on Office of Inspector General (OIG) exclusion – specifically, CMS proposes to include

administrative and management services personnel, such as human resources specialists and accountants, within the purview of the denial or revocation;
- Expanding CMS authority to deny a physician's enrollment if his or her Drug Enforcement Administration (DEA) certificate of registration to dispense a controlled substance is currently suspended or revoked by allowing denial in cases where the physician surrenders his or her DEA certificate in response to an order to show cause;
- Allowing physicians, providers, or suppliers to reverse a revocation against an individual such as an owner or managing employee due to adverse activity if they terminate their relationship with that individual within 30 days;
- Clarifying the deactivation rebuttal process; and
- Increasing flexibility for revocation of physicians, providers, and suppliers engaging in noncompliant billing.

TMA Response
TMA generally supports these efforts since they improve the ability of the agency to identify and remove individuals acting improperly. We have some concerns with physicians being removed from the program due to actions by relatively low-level employees but understand that the agency and OIG will closely examine these individual situations.

We support the proposal to reverse physicians' revocation when they terminate the employee within 30 days but ask the agency to expound on how this impacts a physician's claims during that time frame.

Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)
Summary
When or if two-way video is not available to a Medicare beneficiary, CMS proposes to permanently allow physicians to provide OUD therapy and counseling services using audio-only technology. CMS also proposes that, during and after the public health emergency, OTPs will be required to indicate in a patient's medical record when and why a visit for substance-use counseling or therapy was audio-only.

TMA Response
TMA supports multidimensional strategies to optimize the treatment of pain and works to educate Texas physicians about the latest evidence-based literature on responsible opioid analgesia management with the goal of reducing the risk to patients and enhancing public safety regarding opioid use, misuse, abuse, diversion, and nontherapeutic prescribing. TMA therefore supports the agency's proposal to allow continued use of audio-only technology after the pandemic ends. As proposed, the rule limits use of audio-only to Medicare beneficiaries for whom two-way video is not available. However, even when two-way video is available, some patients may prefer audio-only services for a variety of reasons – convenience, unstable internet connections, and so forth. Audio-only services also may, in fact, increase compliance for people undergoing OUD treatment. Thus, we recommend that the agency allow continued payment for audio-only OUD treatment services regardless of availability of two-way video. As relates to mental health and substance-use disorders, a growing body of literature, including research conducted by the Substance Abuse and Mental Health Services Administration, indicates that virtual care – two-way video and audio-only – has outcomes comparable to in-person care. Thus we believe OTPs should have the discretion to continue using the technology if it is the patient's preference.

However, to ensure equitable use of the modality, we also strongly support continued oversight and research to ensure all Medicare patients, regardless of socioeconomic and geographic background, have access to the technology. TMA also recommends that as the OTPs evolve, services should be paid at parity regardless of service modality, whether in person, audio-visual, or audio only.

Updates to the Physician Self-Referral Regulations

Summary

In the proposed rule, CMS would broaden the definition of indirect compensation arrangements subject to the physician self-referral regulations, or self-referral law, and would also consider changes to the vaccine exemption.

TMA Response

For the proposed rule on indirect compensation arrangements (ICA), TMA recommends that CMS narrow the proposed language that would add a fourth way the individual unit of compensation would qualify the arrangement as an ICA. For the proposed rule on the law's vaccine exemptions, TMA supports allowing the exception to apply to COVID-19 vaccines even if they are not subject to CMS-mandated frequency limits. TMA also supports CMS' alternative proposal to remove the frequency-limits requirement for all vaccines.

Indirect Compensation Arrangements

Generally, self-referral law prohibits a physician from referring certain designated health services to an entity with which the physician has a financial relationship. The prohibited relationships include an ICA.

Under the self-referral law, an ICA exists if three prongs are met. The second prong addresses the aggregate and per-unit compensation necessary for there to be an ICA. For the per-unit compensation, the current rules contain three qualifying types. The proposed rule would add a fourth:

> [P]ayment for anything other than services personally performed by the physician (or immediate family member).

The stated purpose of this addition is to address prior rulemaking's inadvertent exclusion of "arrangements involving unit of service-based payment for the rental of office space or equipment."

However, this broad proposed language would likely encompass arrangements beyond those involving unit-of-service-based payments. If the latter arrangements pose a risk of program abuse, then the ICA definition could be narrowly amended to include those specific arrangements – cf. §411.357(p) – instead of sweeping in all services not personally performed by the physician. This would also be consistent with CMS's previous efforts to simplify the ICA analysis and accordingly reduce unnecessary compliance burdens on physicians.[2]

Vaccine Exceptions

TMA supports efforts to remove barriers to vaccine delivery and supports CMS' proposals to remove regulatory requirements that could limit future distribution of the COVID-19 vaccines and other vaccines.

The physician self-referral law's prohibition on referrals contains an exception for vaccinations in §411.355(h). However, to qualify for the exception, the vaccine must be subject to CMS-mandated frequency limits.

As explained in CMS's proposed rules, COVID-19 vaccines are currently not subject to the physician self-referral law. This is because the vaccines are not a designated health service, due to Medicare not making payment for the vaccines. CMS has also not imposed a mandated frequency limit for the COVID-19 vaccines. However, should COVID-19 vaccines become payable by Medicare in the future – and thus

[2] *See* 85 Fed.Reg. 77545-46 (Dec. 2, 2020) ("We are finalizing revisions to the regulations at §411.354(c)(2) that we believe achieve the same result as the Phase I regulatory construct in protecting against program or patient abuse but reduce unnecessary burden on the regulated industry.").

a designated health service – but not be subject to frequency limits, then the vaccines would not meet the current requirements to qualify for the vaccine exception.

To address the concern that this could impede availability of the vaccine, CMS proposes to amend the vaccine exemption to exclude COVID-19 vaccines from the frequency-limits requirement. Alternatively, CMS proposes to remove the CMS-mandated frequency limit requirement for all vaccines.

TMA supports the proposed removals of required frequency limits for COVID-19 vaccines and for all vaccines. Both proposals would reduce barriers to vaccine delivery.

In the proposed rules, CMS asks whether the removing the requirement for all vaccines would necessitate alternative program integrity requirements. TMA does not believe additional requirements would be needed. Generally, vaccines are administered at discrete intervals, based on age or medical indications.[3] As such, vaccines do not present the same program integrity concerns as other outpatient drugs and can even reduce health care costs by preventing more serious diseases.[4]

Requirement for Electronic Prescribing for Controlled Substances

Summary

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment Act of 2018 requires that Medicare Part D prescriptions for Schedule II, III, IV, and V controlled substances be prescribed electronically starting on Jan. 1, 2021. In 2021, CMS finalized a policy stating the agency would not take compliance actions before Jan. 1, 2022.

In this proposed rule, CMS continues to encourage electronic prescribing of controlled substances (EPCS) adoption and notes that EPCS increased from 38% of prescriptions in 2019 to 70% in 2021. However, CMS proposes to delay compliance actions until Jan. 1, 2023, due to the COVID-19 public health emergency. For patients in long-term care facilities, the EPCS compliance deadline would be 2025. CMS also proposes EPCS exceptions based on prescribing volume, location, disaster declarations, and infeasibility. In addition, CMS proposes that the threshold prescribers would need to meet for compliance is 70% of their controlled substances being sent electronically.

TMA Response

TMA fully supports the proposal to postpone the EPCS compliance by another year to Jan. 1, 2023. Even though Texas began requiring EPCS on Jan. 1, 2021, the state has issued waivers for physicians citing technical or financial hardships. Physicians continue to be overwhelmed and impacted by the COVID-19 PHE, and the delays and waivers are sincerely appreciated. TMA encourages CMS to continue to monitor the viability of practices due to the financial devastation from COVID-19, particularly small and rural primary care practices that regularly operate on thin profit margins.

TMA believes the 70% compliance threshold is reasonable but encourages CMS to phase in the threshold beginning with 50% in year one of compliance, 60% in year two, and 70% in year three. This allows physicians time to adjust, set patient expectations, and ensure industry preparedness.

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[3] See CENTERS FOR DISEASE CONTROL AND PREVENTION. Immunization Schedules (Feb. 11, 2021).

[4] See DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL. OIG Advisory Opinion No. 16-09 (Sept. 23, 2016) ("[T]he Proposed Arrangement focuses on adult vaccines, which are administered in a limited manner. Unlike drugs that are necessary to treat illness and ongoing, chronic conditions, vaccines protect against preventable diseases that could lead to additional and more costly services."); see also DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL. OIG Advisory Opinion No. 11-07 (Jun. 8, 2011) ("[T]he Arrangement is unlikely to result in overutilization. The Requestor certified that administration of the Expanded Vaccine is the standard of care and is universally recommended except where contra-indicated. Thus, the Arrangement is unlikely to induce a health care practitioner to prescribe and administer a vaccine that the practitioner would not otherwise have furnished in the absence of the inducement.").

TMA agrees with the proposed exceptions and urges CMS to finalize exceptions for physicians who prescribe 100 or fewer Part D controlled substance prescriptions per year. This allows physicians who rarely prescribe controlled substances to still have the ability to care for their patients during those rare circumstances without causing undue financial hardship.

TMA agrees that in cases of emergency or declared disaster, an exemption should be available for prescribers in affected ZIP codes and urges CMS to finalize this proposal.

TMA agrees that CMS should grant waivers to prescribers facing extraordinary circumstances such as working in a services area that lacks broadband access. TMA strongly recommends that CMS allow waivers to be renewed annually. A physician who is unable to e-prescribe controlled substances due to economic hardship or technical limitations may not have relief from those barriers after one year.

TMA urges CMS to consider an additional waiver for physicians who prescribe compounded medications that qualify as controlled substances but cannot electronically prescribe the compounded medication because it is not listed on the prescribing software's medication list.

As mentioned, Texas began requiring EPCS effective Jan. 1, 2021. There continues to be confusion among pharmacists who deny paper prescriptions for controlled substances because they incorrectly think all controlled substances have to be sent to the pharmacy electronically. This causes delays in patients receiving their needed medications to get timely relief and healing. TMA suggests that when CMS requires compliance, there should be an accompanying campaign or messaging to pharmacists educating them about the exceptions and waivers, thus allowing pharmacists to fill controlled substances prescriptions when the order is delivered to the pharmacy via paper.

CMS solicited comments on whether penalties or other compliance action should be imposed for not electronically prescribing controlled substances. **While TMA recognizes the value of EPCS, TMA emphatically asks CMS not to impose penalties for noncompliance.** Financial penalties have additional and unintended consequences such as limiting access to care or physicians not prescribing needed medications to patients. CMS should first seek to understand why a minority of controlled-substance prescribers do not use EPCS and help those prescribers move to compliance in a nonpunitive fashion.

Updates to the Quality Payment Program (QPP)

Summary

To adjust for eventual statutory requirements, CMS proposes the following Merit-Based Incentive Payment System performance category weights to be applied to the final score methodology for the 2022 performance year (2024 payment year):

- Quality: 30% (is currently 40% for 2021 performance year);
- Cost: 30% (is currently 20%);
- Improvement activities: 15% (is currently 15%); and
- Promoting interoperability: 25% (is currently 25%).

TMA Response

Physician burnout is a serious consequence for physicians who also operate a small business and must comply with myriad regulations. Physicians' primary mission is to help, treat, and heal their patients who are sick and suffering. Medicare only offers an incentive payment if physicians jump through several hoops to meet ever-changing and numerous requirements for the MIPS program. The proposed changes to the MIPS program are increasingly burdensome and clinically irrelevant. Moreover, it is overwhelming

for physicians to keep track of the constant changes. **TMA urges CMS to not add to the burden and pleads with the agency to tweak MIPS requirements only as needed.** Further, TMA urges CMS to not increase the MIPS performance threshold and instead maintain it at 50 points, especially as physician practices continue to be in the midst of the ongoing COVID-19 pandemic.

MIPS Value Pathways (MVPs) and Subgroups

Summary

CMS proposes seven MVP subgroups set to begin in early 2023: rheumatology, stroke care and prevention, heart disease, chronic disease management, emergency medicine, lower extremity joint repair, and anesthesia. MVP participants will select four, instead of six, quality measures and two medium-weighted or one high-weighted improvement activity. They will be scored only on the cost measures included in the MVP. Starting in 2025, multispecialty groups interested in MVP participation will aim at phasing out MIPS after the 2027 performance year.

TMA Response

Though TMA and CMS are both focused on moving physicians to risk-based systems in voluntary, physician-led advanced alternative payment models (APMs), CMS nevertheless continues to develop MVPs, which Congress did not establish in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The agency professes laudable goals regarding reducing physician burden, yet TMA and other physician stakeholders continue to express concern over the MVP framework and how such reporting tracks may increase physician burden and require unrealistic infrastructural investment. As TMA first commented in a 2019 letter, the MVP Pathways further burden physicians to learn about a new program with different data requirements. Then, in a 2020 letter TMA sent the agency, we argued adding MVPs to a system whose overall foundation is defective only serves to create an increasingly unstable system. Physicians are struggling to keep practices viable during the pandemic; incessant modifications to MVPs and the MIPS program in general only increase these burdens and are untenable.

Given the complexities with MIPS, TMA generally supports CMS' proposal to phase out MIPS after 2027. **Instead of pursuing MVPs, CMS should aggressively focus on the development of voluntary, physician-led alternative payment models. TMA is concerned with recommendations to restrict the number and type of APMs.**

Quality Performance Category

Summary

Starting in 2022, CMS intends to reduce the weight of the quality performance category from 40% to 30% of the final MIPS score. In addition, the CMS Web Interface will be extended as a quality reporting option for registered groups, virtual groups, or other APM entities. Beginning 2023, the data completeness will be increased to 80%.

CMS also proposes changes to the MIPS quality category measure set, addition of new quality measures, updates to specialty sets, removal of existing quality measures, and substantive changes to existing measures.

TMA Response

Especially in the context of a public health emergency, TMA implores CMS to maintain the quality performance category weight at 40% of a MIPS score. TMA supports CMS' proposal to maintain the data completeness criteria threshold at 70% for the 2021 and 2022 MIPS performance periods. TMA urges CMS to consider a cap of 70% on the data completeness criteria until the year after the PHE ends before increasing the threshold. TMA further suggests that CMS continue to monitor data completeness statistics and appropriately adjust the threshold, ensuring physicians in all practice settings can continue to participate equitably. Additionally, increasing the data completeness threshold would result in

increased administrative and cost burdens for physician practices, which is contrary to CMS' Patients Over Paperwork Initiative.

Regarding changes to quality measures, TMA suggests that CMS adhere to the recommendations of the Core Quality Measures Collaborative (CQMC), in which TMA participates. CQMC is a broad-based coalition working to facilitate cross-payer measure alignment through the development of core sets of measures to assess the quality of health care in the U.S.

TMA supports efforts to improve meaningful measurement but opposes the continuous and evolving changes to the measures list in general. Quality performance requires a full calendar year of data, and continuous changes to quality measures often require immediate changes to workflow and data collection operations that are administratively burdensome. TMA also suggests that as substantive changes are made to quality measures, physicians be given a two-year grace period to adjust their processes for measure compliance. Therefore, physicians should be given credit for either the current or future quality measure data collection requirements.

Additionally, TMA urges CMS to maintain a sufficient number of quality measures for physicians who choose to report via claims submission. It is costly and time-consuming for physicians to pay registry and electronic health record (EHR) vendors for quality data submission. Though claims-based reporting has challenges, many physician practices have learned how to report effectively through this method. Vendor submission unnecessarily adds to physician financial and administrative burden associated with the quality category.

Cost Performance Category

Summary

CMS proposes to increase the cost performance category weight to be 30% for the 2022 performance year (2024 payment year).

Further, CMS plans to establish five new episode-based cost measures:

- Two procedural measures: melanoma resection, colon and rectal resection;
- One acute inpatient measure: sepsis; and
- Two chronic condition measures: diabetes, asthma/chronic obstructive pulmonary disease.

These five measures are in addition to the existing two global or population-based measures and the 18 episode-based measures. If a MIPS-eligible clinician meets eligibility for facility-based measurement but participates in MIPS as an individual or group, the higher final score between the facility-based scoring and MIPS submission-based scoring will be used.

TMA Response

TMA appreciates CMS' awareness of challenges stakeholders may encounter and ways to ensure that stakeholder-developed cost measures meet certain standards and are consistent with the goals of MIPS and MVPs. **We oppose the cost weight being increased to 30% and urge CMS to delay increases to it until the end of the public health emergency. Instead, CMS should maintain the quality performance category weight at 40% of a MIPS score.** Further, TMA cautions CMS that the cost category is administratively burdensome to many physicians, and building further complexities into this category exacerbates the burden. It is important for physicians in all practice settings to be able to access the data used to score the cost category. This requires having the ability to access and import into the EHR real-time information from labs, pharmacies/pharmacy benefit managers, hospitals, and/or rehabilitation services. CMS should ensure that small practices are not disadvantaged by the cost category.

Improvement Activities Category

Summary

CMS proposes to maintain the improvement activities performance category weight at 15% for the 2022 performance year (2024 payment year). Beginning with the 2022 performance period CMS proposes to:

- Revise group reporting requirements;
- Revise the time frame for improvement activities nominated during the public health emergency;
- Revise required criteria for improvement activity nominations;
- Suspend all activities that raise possible safety concerns or become obsolete from the program when this occurrence happens outside of rulemaking;
- Add seven new improvement activities, modify 15 existing improvement activities, and removed six previously adopted improvement activities;
- Revise the "Drug Cost Transparency to Include Requirements for Use of Real-Time Benefit Tools" improvement activity; and
- Add the COVID-19 "Clinical Data Reporting With or Without Clinical Trail" improvement activity.

TMA Response

TMA agrees with CMS' approach to revising group reporting requirements so that multispecialty groups can report in subgroups while meeting the 50% threshold and still choose measures that are meaningful and applicable to the specialists within that group. TMA appreciates that CMS reviews the types of inquiries received through the Quality Payment Program help desk and reacts to the needs of physicians and other participants seeking to comply with the complex details of the program.

Because TMA does not historically nominate improvement activities for inclusion, we encourage CMS to heed the suggestions of those organizations that submit nominations so that interested stakeholders have a fair voice in the process.

Due to a circumstance where an improvement activity had expired and had to be removed during the calendar year, CMS proposes to promptly remove improvement activities outside of the rulemaking process. TMA agrees there should be a mechanism for promptly suspending an improvement activity, especially if there is potential for patient harm. TMA further agrees that CMS should use all communication channels to alert QPP participants that the activity is suspended. However, CMS should not penalize physicians who report on a suspended activity. CMS should allow any suspended activities to still count when the suspension happens outside of rulemaking.

CMS is adding seven new improvement activities, three of which are related to promoting health equity and better identify social determinants of health. TMA appreciates CMS' commitment to achieving equity in health care outcomes for patients by supporting physicians in quality improvement activities to reduce health inequities and enabling them to make more informed decisions. CMS is also modifying 15 current improvement activities and removing six previously adopted improvement activities. **TMA remains concerned that physicians are continuously challenged with compliance in an ever-changing and increasingly complex program.** TMA urges CMS to only modify and remove activities when absolutely necessary.

Promoting Interoperability Performance Category Performance Period

Summary

CMS proposes to maintain the promoting interoperability performance category at 25% for the 2022 performance year (2024 payment year). CMS does not propose any changes to the promoting interoperability performance period of 90 days as established by the agency in previous rulemaking.

TMA Response
TMA appreciates the continuation of the 90-day performance period for the promoting interoperability category. As stated in the proposal, it is an appropriate performance period and offers consistency and stability to this category.

Proposed Changes to the "Query of Prescription Drug Monitoring Program (PDMP)" Measure Under the Electronic Prescribing Objective
Summary
CMS proposes to maintain the electronic prescribing objective measure, "Query of Prescription Drug Monitoring Program (PDMP)," as optional and worth 10 bonus points for 2022.

TMA Response
TMA supports and appreciates CMS' proposal to maintain the query of PDMP measure as optional and worth 10 bonus points in the MIPS promoting interoperability category.

While TMA agrees that checking the PDMP provides clinical value at the point of care, the ability to track this measure can become burdensome to physicians. Texas generally requires that physicians check the state prescription monitoring program (PMP) prior to prescribing opioids, benzodiazepines, carisoprodol, or barbiturates. For two years, Texas funded the integration of Appriss' PMP check via the EHR. This gave physicians access to the patient's medication history for the previously mentioned drug classes at the point of care and within the physician's workflow. The Texas funding for this integrated EHR access expired Sept. 1, 2021. Now physicians must bear that extra cost for integrated access or spend extra time by leaving their EHR and logging into PMP Aware to check their patient's prescribing history. Some EHRs automatically denote that the PMP was checked while others require manual documentation. If a physician does not document the PMP check, an audit could be performed indicating the PMP was checked. For these reasons, TMA appreciates that CMS is reducing physicians' burden by keeping Query of PDMP an optional and bonus measure.

CMS sought comment on the future of the Query of PDMP measure. While TMA believes most physicians are able to respond to this measure with a yes-or-no attestation, it is important that CMS maintain an exclusion for physicians who do not prescribe controlled substances of the aforementioned four drug classes.

Proposed Changes to the "Provide Patients Electronic Access to Their Health Information Measure" Under the Provider-to-Patient Exchange Objective
Summary
CMS proposes that, beginning in 2022, clinicians are required to make patient health information (PHI) available indefinitely starting with encounters on or after Jan. 1, 2016.

TMA Response
TMA strongly opposes CMS' proposal that physicians be required to make patient health information available indefinitely starting with encounters on or after Jan. 1, 2016.

Expecting physicians to indefinitely maintain patient health information adds a financial and workforce burden that is not feasible. This proposed requirement is a far reach beyond what Congress intended when MACRA was designed. This kind of government overreach will frustrate physicians and patients, and cause further physician burnout and other unintended consequences. TMA does not believe it was the intention of Congress or is within the authority of CMS to supersede all state medical record retention laws in the U.S. In addition to cost concerns and physician burden, there are privacy concerns associated maintaining the troves of data called for by this requirement.

CMS should cite peer-reviewed scholarly studies supporting the concept that all patient data should be retained retroactively and indefinitely. For example, a hospital stay may produce hundreds of data points, some of which may be valuable while many may not be. Physicians need access to clinically useful information and should not have to navigate through countless pages of dated PHI. CMS should support industry efforts identifying what data should be retained, archived, or discarded.

As part of the information-blocking regulations under the 21st Century Cures Act, the U.S. Department of Health and Human Services (HHS) established April 5, 2021, as the date that physicians were required to make U.S. Core Data for Interoperability (USCDI) data available to patients. TMA encourages CMS to maintain this HHS start date and limit the PHI availability requirements to USCDI data. In October 2022, physicians are required to make all data available to patients. **TMA strongly encourages CMS to fully align with 21st Century Cures Act date and data requirements.**

Additionally, the proposed indefinite and retroactive (to Jan. 1, 2016) date is infeasible and ill-advised:

- Physicians may have switched EHRs, no longer have the patient data available on the active portal, and have no way to convert the data into the needed format due to the proprietary nature of EHRs.
- State medical boards set time limits for which physicians must retain medical records. In most cases in Texas, it is seven years from the date of last treatment for adult medical records and seven years from date of last treatment or until the patient reaches 21, whichever is later, for pediatric medical records.
- Electronically maintaining patient records indefinitely is simply not feasible as this requires additional data storage that can impact an EHR's performance and increases data storage costs.

Instead, TMA encourages CMS to support the development of a universal patient portal through which patients can easily send and access their data regardless of which EHR their physician(s) and other providers use. This would allow patients desiring to maintain a lifelong, longitudinal medical record a way to store and access their records. Physicians should **not** be unduly burdened with maintaining electronic records indefinitely.

Modifications to the Public Health and Clinical Data Exchange Objective

Summary

CMS proposes to require the immunization registry and electronic case reporting measures under the public health and clinical data exchange objective. CMS indicates there are gaps in exchanging data with public health agencies and that a more assertive approach is needed.

TMA Response

TMA suggests that a better approach is for CMS to retain the five public and clinical health registries as currently scored due to the challenges outlined below.

If CMS finalizes the proposal to convert the immunization registry reporting to a required measure, the requirement should apply **only** to the ability to send data to the state's immunization information system. In Texas, additional immunization registry consent requirements make it challenging for EHR vendors to support the bidirectional exchange of data between immunization information systems and physician practices. TMA has advocated heavily for Texas to change its consent requirements to a simple yes/no and will continue to do so. Until EHR vendors can support bidirectional exchange in all jurisdictions, CMS should not require it.

TMA encourages CMS to conduct an environmental scan of public health case reporting readiness and the ability of physician practices to efficiently connect to these registries. CMS should ensure industry

readiness prior to requiring the reporting of electronic case measures. TMA appreciates the continuance of the exclusion but still recommends keeping this measure as optional.

Safety Assurance Factors for EHR Resilience (SAFER) Guides

Summary

CMS proposes to require that physicians attest "yes" to having conducted an annual self-assessment of the high-priority practices listed in the Office of the National Coordinator for Health Information Technology's (ONC's) SAFER Guides.

TMA Response

TMA recommends that CMS make the SAFER Guides attestation an optional bonus measure for conducting an annual self-assessment of the high-priority practices listed in ONC's SAFER Guides. Additionally, TMA recommends that CMS add the annual SAFER Guides self-assessment as an activity in the improvement activities category of MIPS.

TMA believes the SAFER Guides are a useful tool in physician practices. In fact, TMA has encouraged the use of the SAFER Guides since their development in 2016. With COVID-19 once again surging, this is not the time for CMS to add new required measures. At the very least, new measures should be optional with bonus points for the first two years while the industry acclimates to the new measures.

Proposed Changes to the Attestation Statements

Summary

In 2017, CMS finalized three attestation statements for MIPS eligible clinicians. These are:

- *Statement A:* Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.
- *Statement B:* Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: (1) Connected in accordance with applicable law; (2) compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria; (3) Implemented in a manner that allowed for timely access by patients to their electronic health information; and (4) Implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers, including unaffiliated providers, and with disparate certified EHR technology and health IT vendors.
- *Statement C:* Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers, and other persons, regardless of the requestor's affiliation or technology vendor.

CMS proposes to reduce the required attestation statements physicians must make to only statement A.

TMA Response

TMA agrees with CMS that attestations statements B and C are no longer necessary since physicians are now required to comply with the 21st Century Cures Acts information-blocking regulations and both statements. TMA thus supports the removal of attestation statements B and C.

Reweighting the Promoting Interoperability Performance Category for MIPS-Eligible Clinicians in Small Practices

Summary

Citing the desire to support small practices and help them successfully participate in MIPS, CMS proposes to temporarily not require an application from physicians and small practices seeking to qualify for the small practice hardship exception and reweighting.

CMS seeks comments to understand why physicians in small practices are not submitting a hardship application and not attesting to promoting interoperability.

TMA Response
TMA fully supports and thanks CMS for the proposal to not require small practices to submit a hardship application for exemption from promoting interoperability. Thus physicians who do not submit data or attest to promoting interoperability would automatically have their MIPS promoting interoperability category set to zero and reweighted to another MIPS category. If a physician in a small practice chooses to submit data, then the physician would be scored appropriately based on data and attestations submitted.

As to why small practices are not submitting hardship applications or attesting to promoting interoperability, TMA frequently hears from physicians and practices who are overwhelmed and confused by the ever-changing details of the MIPS program. This is further exacerbated as many face significant financial and physical hardships during the public health emergency.

Other MIPS Policies
Summary
The final scores for all MIPS-eligible clinicians for a prior period must be either the mean or median of the final scores. This will begin in year six of MIPS (2024 MIPS payment year). CMS proposes to establish the performance threshold at 75 points and increase the additional performance threshold from 85 to 89 points.

Recognizing the effects of the COVID-19 PHE, CMS proposes to continue doubling the complex patient bonus for the 2021 MIPS performance year/2023 MIPS payment year.

TMA Response
Physicians will continue to struggle complying with the MIPS requirements as the performance threshold continues to increase. And in many cases, the quality performance category could be lower than the performance threshold for a group. TMA appreciates CMS' attempt to make the intention known to report to MIPS as a group before potential eligibility is expanded to other members of the group.

TMA appreciates CMS recognizing the impact of the public health emergency. We support proposals to continue to double the complex patient bonus score MIPS participants can receive during the 2021 performance period.

Projected 2022 MIPS Participation and 2024 Payment Adjustments
Summary
CMS states that 809,625 clinicians will be MIPS-eligible in 2022. The payment adjustments stemming from the 2022 performance period will be applied to the 2024 Medicare payments. The maximum positive payment adjustment, including the exceptional bonus, is estimated to be 14%, while the maximum penalty is 9%.

TMA Response
TMA supports CMS' recognition of the 75-point performance threshold as an attainable goal and that more clinicians will receive a positive adjustment than a negative adjustment.

Alternative Payment Models

Summary

CMS proposes changes to the Quality Payment Program to promote the adoption of alternative payment models. CMS proposes changes in how to increase the likelihood of making incentive payments in a timely manner by changing how it accesses the taxpayer identification number information for qualifying APM participants. A team-based approach to care is increasing in APMs, allowing physicians and NPPs in the same group to provide better continuity of care. This instills close collaboration and an element of coordination in providing care to the beneficiary.

TMA Response

TMA and CMS are both focused on moving physicians to risk-based systems in voluntary, physician-led advanced alternative payment models. To be blunt, TMA considers the frequent, never-ending, and complicated changes the agency annually proposes for the MIPS and MVP pathways to dramatically increase the attractiveness of participating in the QPP via APMs. **Therefore CMS should aggressively focus on the development of voluntary, physician-led alternative payment models.** TMA is concerned with recommendations by the Medicare Payment Advisory Committee to restrict the number and types of APMs. This recommendation does not align with and would therefore delay Congress' intent to create physician payment models that add incentive payments to provide high-quality and cost-efficient care to a specific clinical condition, a care episode, or a population.

Chiquita Brooks-LaSure
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Re: Medicare Program: CY 2022 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies

Dear Administrator Brooks-LaSure:

The Inter Organizational Practice Committee (IOPC) is a coalition of representatives of all of the major Neuropsychology organizations in the US including the American Academy of Clinical Neuropsychology (AACN), Division 40 of the American Psychological Association, the National Academy of Neuropsychology (NAN), and the American Board of Professional Neuropsychology (ABN), as well as the American Psychological Association Services, Inc. The IOPC is tasked with coordinating national neuropsychology advocacy efforts, and represents approximately 8,000 neuropsychologists in the United States.

Over the years, the IOPC has joined forces on numerous occasions to pool resources and expertise nimbly and rapidly on advocacy issues to improve the practice climate and access to high quality neuropsychological care for our patients. As requested by the Centers for Medicare and Medicaid Service (CMS), the IOPC is providing comments on the proposed rule on the 2022 Medicare physician fee schedule released on July 13, 2021.

The COVID-19 public health emergency (PHE) forced neuropsychologists to find new ways to meet the needs of their patients as leaving home put seniors and those with co-morbid conditions at risk of being exposed to the virus. Without the waivers extending the use of telehealth in Medicare beneficiaries would have lost access to mental and behavioral health services at a time when their health, both physical and mental, was extremely vulnerable.

IOPC thanks CMS for the flexibility extended under the waivers, such as making the home an originating site, adding more services to telehealth, and allowing patients to use audio-only devices. IOPC believes the next step is to ensure that flexibility remains available to Medicare beneficiaries after the PHE comes to an end.

<u>IOPC recommends the following:</u>
Make neurobehavioral status exams and feedback sessions for psychological and neuropsychological testing evaluations available as audio-only telehealth services.

Audio-only Neurobehavioral Status Examination (NSE) services under codes 96116 & 96121 improve access and facilitate care, particularly for senior, fragile, and disabled populations. For example, audio-only NSE is critical for accessing patients who may be hard to reach otherwise due to mobility issues, transportation barriers, inadequate network connectivity, and/or insufficient technology skills. The NSE is the crucial first step when determining the appropriateness of providing Neuropsychological Assessment for a given patient, for developing an individualized battery of tests, and for deciding optimal scheduling parameters. Limiting the NSE to virtual and in-person only creates an overly burdensome hurdle that will preclude a high percentage of senior, fragile, and disabled patients, who specifically need neuropsychological testing for accurate diagnosis and care planning, from getting this evaluation. With limited exception, the Neurobehavioral status exam (NSE), can readily be conducted by audio-only. The NSE includes the clinical assessment of thinking, reasoning, and judgment with a qualified healthcare provider verbally assessing acquired knowledge, attention, language, memory, planning, and problem solving. Barriers to completing the NSE by audio-only method are comparable to barriers encountered when completing the NSE by face-to-face or by audio-visual methods, including assessing patients with hearing loss or aphasia. Clinical assessment of visuo-spatial abilities would be deferred to the in-person or audio-visual Neuropsychological Assessment.

Feedback sessions for psychological and neuropsychological testing evaluation under codes 96130-96133 should also be available as audio-only services. A post-evaluation interactive feedback session with the patient and/or family members is a typical part of the neuropsychological and psychological evaluation. It is empirically shown to produce clinically meaningful benefits including symptomatic, quality of life, social adjustment improvements, better ability to cope with their condition, decreased healthcare utilization receiving test results is highly valued, not only by patients but also physicians who refer their patients for neuropsychological assessments.
The interactive feedback session typically emphasizes any, or all, of the following:

- Discussion of the relationship between test results and information about diagnosis and prognosis.
- Patient education about their diagnosed condition and functioning with the goal of improving adherence to treatment plans, and safety.
- Explanation of treatment recommendations. In addition to those recommendations that are directly managed by the patient's medical provider (e.g., changes in medication or treatment), patients are provided with evidence-based treatment recommendations that are not typically managed by medical providers, and which are best explained by providers with expertise in neuropsychological or psychological assessment, including tailored behavioral strategies to maximize functioning, safety measures such as driving recommendations, referrals to other specialty providers (e.g., psychiatry, rehabilitative therapists), recommendations for nonpharmacological interventions, and community resources that assist in optimizing treatment and prognosis.
- Communication of results in the presence of family members in order to explain treatment recommendations, which enhances treatment outcome for the patient, and – for patients with dementia – may result in up to an 18-month delay in nursing home placement when caregivers are provided with education and connected to caregiver resources. In some cases, a patient may be undergoing treatment or may be too cognitively impaired to engage in feedback. In such circumstances where the physician or QHP determines that feedback is necessary to ensure adherence to treatment plans including safety issues, feedback may be given to the patient's caregiver (with appropriate permissions and release of information).

With respect to audio-only telehealth services, IOPC recommends the following:

- Avoid imposing an in-person requirement for telehealth, either before or after the first telehealth visit, as there is no clinical evidence for an arbitrary in-person requirement before a patient can access telehealth. Since the start of the PHE, mental and behavioral health providers have successfully furnished services to patients via audio-only technology. Adding an in-person visit is burdensome for current patients and will discourage new ones from seeking help. As noted in the commend letter from the American Telemed Association (ATA), there is currently a shortage of 6,000 mental health providers in the U.S. and that number is expected to grow significantly over the next ten years. CMS will impede access to mental and behavioral health care if it imposes unnecessary requirements on telehealth services.
- Not require additional documentation in the medical record supporting audio-only services. The documentation in the medical record already provides the information needed to justify medical necessity for the service. In addition, through the proposed use of a modifier providers will be self-certifying that they have two-way audio-visual telecommunications devices but it is the patient who needs or wants to receive the service via audio-only. No other documentation should be required.
- Not preclude high-level services such as psychotherapy for crisis from being furnished through audio-only telehealth. By definition a crisis is immediate and help is required as soon as possible. There should be nothing that delays or discourages immediate contact with the provider and audio-only telephones are the easiest telecommunications devices for many beneficiaries to access.

Adopt the proposal allowing all psychological and neuropsychological testing services to be provided via telehealth through the end of CY 2023. Add the codes for developmental testing and adaptive behavior services to be provided via telehealth through the end of CY 2023

IOPC supports the proposal to allow psychological and neuropsychological testing services to remain under telehealth through 2023 as it will protect beneficiaries from suddenly losing access to critical services when the PHE ends. IOPC is asking CMS to also allow services for developmental testing and adaptive behavior services to continue until the end of 2023 so that patients do not lose access to critical services and to allow stakeholders time to demonstrate why these services should remain available through telehealth.

CMS must work with Congress to avoid a 3.89% cut to the 2022 Conversion Factor.

IOPC urges CMS to work with Congress to avoid the losses all clinicians will incur if CMS is forced to meet budget neutrality requirements. Reducing the conversion factor in 2022 as CMS is proposing will be a significant loss for many providers. Following the 3.3% loss providers incurred in 2021, even after the additional 3.75% added by Congress which expires at the end of this year, will result in a combined reduction of over 7% in two years.

Retain traditional MIPS for those providers for whom no MVPs are relevant or are not feasibly able to be implemented. Reduce the number of quality measures reported from 6 to 4 to align with MVPs and give providers options in selecting measures most meaningful to their patients.

We understand that CMS is looking at ways to promote quality and value in health care and we support efforts that improve the quality of mental and behavioral health care service. Unfortunately, in the QPP, this has resulted in reporting programs that are constantly changing. PQRS turned into MIPS which CMS now wants to turn into MIPS Value Pathways (MVP), sunsetting traditional MIPS by 2028. The

constant revision of Medicare's reporting programs has left many ECs frustrated and uncertain about their future in Medicare. ECs have devoted time, energy, and money to accurately report under these systems only to be told every few years the requirements are changing. Constituents of IOPC have been working hard with APA's Mental and Behavioral Health Registry (MBHR), to develop quality measures that best reflect clinical practice and improved patient outcomes without being given the necessary time for provider education, implementation, and adoption due to the constant programmatic changes. As a result, many psychologists have left Medicare altogether, citing the struggle to find and implement measures that match their practices to avoid incurring a penalty that will decrease their already low Medicare reimbursement. This departure threatens vital psychotherapy, testing and integrated care for older Americans and people with disabilities.

We ask that CMS carefully consider our recommendations outlined below.

- **Retain the current minimum performance threshold**

The minimum performance threshold based upon the mean or median of the final scores of all MIPS eligible clinicians (ECs) is an unfair standard to apply to psychologists who have relatively few measures to choose from and are limited in their ability to report Promoting Interoperability (PI) due to exclusion from the legislative funding for electronic health technology provided through Meaningful Use. This leaves psychologists with far fewer opportunities to amass points compared to ECs in other specialties.

We are asking CMS to retain the current minimum performance threshold of 60 points for MIPS reporting and not adopt its proposal to raise the number to 75. It will be extremely difficult for psychologists to increase their number of points by 25% in just one year to avoid a 9% penalty.

- **Retain bonus points for high priority measures**

We believe CMS should continue to provide bonus points for reporting outcome/patient experience measures and high priority measures beyond the 1 that is required. Removing the opportunity to receive bonus points at the same time that the agency is proposing to raise the current minimum performance threshold is increases the risk that many ECs will face a penalty rather than securing a neutral or positive payment adjustment. Additionally, outcome/patient experience measures and high priority measures are generally in the best interest of the patient in terms of quality care and should be encouraged and rewarded with bonus points. Retaining bonus points also aligns with stated goals by CMS to move away from reporting process measures and prioritizing the reporting of outcome measures, which are more difficult to implement due to barriers related to workflow burden and the aforementioned lack of EHR adoption attributed to the omission of psychologists from federal EHR incentive funding.

- **Quality Measure Scoring**

We strongly support establishing a 5-point floor for the first 2 performance periods for new measures submitted that meet the data completeness requirement assuming this includes QCDR measures. We recommend that this 5-point floor be retroactive for measures introduced in 2020 and 2021 and that measures introduced in performance year 2020 have an additional performance (PY 2022) due to the extreme and uncontrollable circumstances policies in effect for PY 2020. New measure adoption can be a challenging process due to workflow and documentation barriers and the uncertainty around benchmarks are a deterrence for providers to choose new measures despite the measure's specialty relevance and likelihood to result in improved quality of care.

We support retaining the 3-point floor for small practices and also recommend retaining the 3-point floor for any measures without a benchmark that were introduced during PY 2020 due to the extreme and uncontrollable circumstances policies in effect for that reporting period.

- **Improvement Activities**

We support the addition of new Improvement Activities designed to promote health equity and clinician well-being.

- **Promoting Interoperability**

We request clarification regarding the proposal by CMS to automatically reweight the PI category for clinical social workers and ECs in small practices. We are asking CMS to confirm that psychologists and certain other non-physician ECs will continue to have the PI category reweighted to zero given that, as noted above, they never had the opportunity to receive federal funds to invest in electronic health records. It is critical that all psychologists, including those in practices with more than 15 ECs, continue to have the PI category reweighted to zero unless they choose to report PI measures or are provided with federal funding to invest in electronic health records.

We also request that CMS implement Section 6001 of the SUPPORT Act (PL 115-271). Section 6001 amends Social Security Act (SSA) Section 1115A(b)(2)(B) to expand the list of models that CMMI may test to include a model that provides incentive payments to behavioral health providers, as specified, in exchange for the providers' adopting and using certified EHR technology to improve care coordination and quality.

- **The transition from MIPS to MIPS Value Pathways**

We appreciate the desire by CMS to address providers' concerns regarding quality payment reporting burden. MIPS Value Pathways, which are essentially core measure sets, may address this burden but are only likely to be feasibly developed for certain settings, such as long term care, or for certain subspecialty provider populations, such as neuropsychologists. MVPs are not likely to be feasibly implemented for psychologists who have generalist practices and see between 30 – 40 patients per week who present with various different diagnoses (e.g., depression, anxiety, PTSD, psychosis, etc.) and represent patients across the lifespan. One core measure set, or MVP, would not be able to account for the level of patient heterogeneity a generalist psychologist provides treatment to, and having to implement multiple different MVPs would actually increase the burden that ECs currently experience with traditional MIPS. One solution would be to retain traditional MIPS for those providers for whom no MVPs are relevant or are not feasibly able to be implemented and instead reduce the number of quality measures reported from 6 to 4 to better align with MVPs and reduce burden while giving providers adequate options in selecting the measures that are most meaningful to their particular patient population.

As noted above, psychologists and certain other non-physician ECs, have been at a severe disadvantage regarding the use of electronic health records since being left out of Meaningful Use. It was for this reason that CMS has been reweighting the PI category to zero for their reporting under MIPS. With the MVP program approach to hold the PI category as a foundation to promote moving to digital quality measures, psychologists are at high risk of failure, risking both a loss in reimbursement and being viewed as not delivering quality services. We fear that too many psychologists will find the new MVP requirements increasingly burdensome and that the program will continue to drive them out of Medicare.

We are also concerned that the timeline for moving ECs from MIPS to MVP does not allow specialties enough time to develop relevant MVP models. Currently, there are no model MVPs that psychologists could use and the prospects for developing MVPs that work for all psychologists by 2023 is daunting, if not impossible as outlined above. Further, there are currently no cost measures for mental and behavioral health, again a foundational component of MVPS, and those that have been developed to date were rejected. Additionally, this transition places an excess burden on qualified clinical data registries (QCDRs) to be ready for MVP reporting by 2023. The self-nomination process and publication of the final rule and approved QCDR measures timelines leave precious little time for vendors to implement and

be ready for traditional MIPS as it stands. Adding MVP reporting into the mix will only complicate an already difficult preparation process.

IOPC wishes to thank CMS for this opportunity to provide comments on the proposed rule involving changes to payment policy under the 2022 Medicare physician fee schedule. We welcome any questions that you might have about the concerns outlined in this letter, and we would be happy to provide you with any additional information that you might find to be helpful (jwoodhouse@gaylord.org; 203.741.3413).

On behalf of the American Academy of Clinical Neuropsychology (AACN), Division 40 of the American Psychological Association, the National Academy of Neuropsychology (NAN), and the American Board of Professional Neuropsychology (ABN), as well as the American Psychological Association Services, Inc

Thank you for your time and consideration.

Respectfully submitted,

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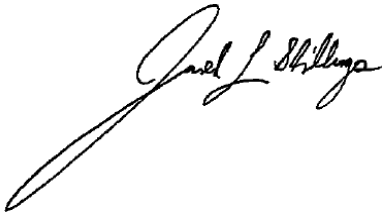
President, National Academy of Neuropsychology

Rick Naugle, Ph., ABPP-CN
President, American Academy of Clinical Neuropsychology



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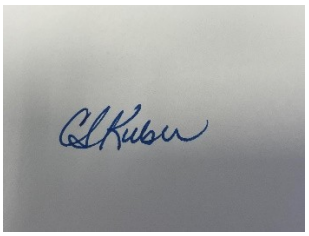

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AMERICAN PSYCHOLOGICAL ASSOCIATION SERVICES, INC.

September 13, 2021

Chiquita Brooks-LaSure
Administrator
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CMS-1751-P
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Re: Medicare Program: CY 2022 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies

Dear Administrator Brooks-LaSure:

I am writing on behalf of the American Psychological Association (APA) to provide comments on the proposed rule on the 2022 Medicare physician fee schedule (PFS), released by the Centers for Medicare and Medicaid Services (CMS) on July 13, 2021.

APA is the largest scientific and professional organization representing psychology in the United States, with a membership of nearly 122,000 researchers, educators, clinicians, consultants, and students. APA seeks to promote the advancement, communication, and application of psychological science and knowledge to benefit society and improve lives.

Psychologists provide Medicare beneficiaries with critical mental health, substance use, and health behavior services including psychotherapy, psychological & neuropsychological testing, and health behavior assessments and interventions. Psychologists are the leaders in mental and behavioral health and pioneered the development of health and behavior services to enable the mental health workforce to assist patients struggling with physical health problems.

Executive Summary of APA's recommendations on key issues

- Remove the originating site requirements and allow audio-only telehealth services for mental health, substance use, and health behavioral services after the public health emergency (PHE) ends.
- Allow coverage of Health Behavior Assessment and Intervention services, feedback sessions for psychological and neuropsychological testing evaluations, and neurobehavioral status exams as audio-only telehealth services.
- Avoid imposing additional requirements - such as periodic in-person visits or additional documentation other than a modifier - for coverage or reimbursement of mental or behavioral health services furnished via telehealth.
- Do not exclude coverage or reimbursement of high-level psychotherapy services furnished via audio-only telehealth.

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Advocating for APA members and psychology

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- Adopt the proposal allowing all psychological and neuropsychological testing services to be provided via telehealth through the end of CY 2023.
- Add the codes for developmental testing and adaptive behavior services to be provided via telehealth through the end of CY 2023.
- Add multiple family group psychotherapy (90849) to Medicare's permanent telehealth list.
- Work with Congress to avoid a 3.89% cut to the 2022 Conversion Factor.
- Allow patients in Federally Qualified Health Centers and Rural Health Clinics to access audio-only telehealth services for mental health, substance use, and health behavior.
- Continue to allow direct supervision of "incident to" services through audio-visual technology after the PHE ends.
- Adopt the codes for Remote Therapeutic Monitoring and reimburse these services at the same rate as the Remote Physiological Monitoring codes they resemble.
- Continue to reimburse telehealth services, including audio-only services, at the non-facility rate.
- Develop new CPT codes to capture the resources involved in furnishing comprehensive multidisciplinary pain services.
- Retain traditional MIPS for those providers to whom no MVPs are relevant or are not feasibly able to be implemented.
- Reduce the number of quality measures reported from 6 to 4 to align with MVPs and give providers options in selecting measures most meaningful to their patients.

Health Equity

CMS should continue its efforts to close gaps in access to mental health, substance use, and health behavior services. Many of the provisions in this Proposed Rule on telehealth, for example, would enable patients from underserved communities - such as rural communities, individuals with disabilities, and communities of color - to access these critical services, often for the first time. People with disabilities frequently face transportation barriers to receiving in-person care or experience heightened anxiety during in-person appointments and require the familiarity of their own homes to fully engage in treatment. The availability of audio-only telehealth is also beneficial to many older patients who may lack the familiarity with the technology necessary for an audio/video telehealth appointment.

Telehealth

The COVID-19 public health emergency (PHE) forced mental health, substance use, and health behavior providers to find new ways to meet the needs of their patients, as leaving home put everyone at risk of exposure to the virus. Without the waivers expanding the availability of telehealth services, Medicare beneficiaries would have lost access to mental health, substance use, and health behavior services at times when their physical and mental health were at risk.

APA thanks CMS for the flexibility extended under the waivers, which have temporarily allowed the patient's home to be considered an originating site, added services to the list of those covered as telehealth, and allowed patients to use audio-only devices. APA believes these treatment options and flexibilities should remain available to Medicare beneficiaries after the PHE comes to an end.

One payment issue not directly addressed by CMS in the proposed rule is whether the agency will continue to pay for telehealth services at the same rate as in-person visits once the PHE ends. For mental health, substance use, and health behavior providers, whose patients are the most frequent users of telehealth, it would be a costly reduction to have their services paid at the facility rate, as done before the PHE waivers. Such a loss in payment will discourage many providers from

continuing to offer telehealth services, jeopardizing access to mental health, substance use, and health behavior services for many beneficiaries. For CMS, the cost of paying for these services at the non-facility rate will be offset by Medicare no longer paying originating site fees for services provided in patients' homes. For these reasons, APA strongly asks CMS to continue reimbursing providers for telehealth services, including audio-only, at the non-facility rate.

Audio-only services

APA appreciates CMS' acknowledgment in the proposed rule that many beneficiaries now rely on audio-only communication technology to receive mental health, substance use, and health behavior services and that terminating audio-only services at the end of the PHE could have a negative impact on access to care.

CMS proposes to allow audio-only communication technology for the diagnosis, evaluation, or treatment of a mental health disorder for a patient who is in their home and does not have, or does not consent to using, two-way audio-visual technology. CMS proposes requiring that the patient receive an in-person visit from the provider within the 6 months before, and possibly after, the telehealth service.

We support allowing patients to continue to receive audio-only services in their homes. However, we believe the proposal should be expanded to include behavioral health services under the Health Behavior Assessment and Intervention (HBAI) codes (96158 – 96171). Like psychotherapy for mental health disorders, health and behavior services do not require visualization of the patient and can be successfully furnished through audio-only technology. CMS should permanently remove the originating site requirements and continue allowing audio-only services for behavioral health services under the HBAI codes. Additionally, APA encourages CMS to ensure that audio-only services will also be allowed for the treatment of substance use.

Similarly, as discussed in our December 16, 2020, letter to CMS (Attachment A), psychological and neuropsychological testing evaluation under codes 96130-96133 should also be available as audio-only services. A post-evaluation interactive feedback session with the patient and/or family members is a typical part of the neuropsychological and psychological evaluation and has been shown to produce clinically meaningful benefits including improvements in symptoms, quality of life, and social adjustment, improved ability to cope with their condition, and decreased healthcare utilization. Receiving a full explanation of test results is highly valued by patients and referring physicians alike.

Interactive feedback sessions typically include:

- Discussion of the relationship between test results and information about diagnosis and prognosis;
- Patient education about their diagnosed condition and functioning with the goal of improving safety and adherence to treatment plans;
- Explanation of treatment recommendations, including patient-specific behavioral strategies to maximize functioning, safety measures such as driving recommendations, referrals to other specialty providers (e.g., psychiatry, rehabilitative therapists), and recommendations for nonpharmacological interventions and community resources to assist in optimizing treatment and prognosis; and
- Communication of results in the presence of family members to explain treatment recommendations, facilitate collection of feedback on treatment effectiveness, and support adherence to treatment.

This engagement and communication enhance treatment outcomes and, especially for patients with dementia, may delay nursing home placement by as much as 18 months when caregivers are provided with education and connected to caregiver resources. In some cases, a patient may be undergoing treatment or may be too cognitively impaired to engage in feedback. In circumstances where the physician or QHP determines that feedback is necessary to ensure adherence to treatment plans including safety issues, feedback may be given to the patient's caregiver with appropriate permissions and release of information.

Neurobehavioral Status Examination (NSE) services (codes 96116 and 96121) can be delivered audio-only. NSE services improve access and facilitate care, particularly for senior, fragile, and disabled populations, and audio-only access is critical for patients facing mobility issues, transportation barriers, difficulties with network connectivity, and lack of technical expertise accessing services via audio-visual telehealth. The NSE is the crucial first step when determining the appropriateness of providing Neuropsychological Assessment for a given patient, for developing an individualized battery of tests, and for deciding optimal scheduling parameters. Limiting the NSE to virtual and in-person only creates an overly burdensome hurdle that will preclude a high percentage of senior, fragile, and disabled patients who need neuropsychological testing for accurate diagnosis and care planning from receiving this evaluation. With limited exception, the NSE can readily be conducted by audio-only telehealth. The NSE includes a clinical assessment of thinking, reasoning, and judgment with a qualified healthcare provider verbally assessing acquired knowledge, attention, language, memory, planning, and problem-solving. Barriers to completing the NSE by audio-only method are comparable to barriers encountered when completing the NSE by face-to-face or by audio-visual methods, including assessing patients with hearing loss or aphasia. Clinical assessment of visuo-spatial abilities, if required for a particular patient, would be deferred to the in-person or audio-visual Neuropsychological Assessment.

In response to other questions raised in the proposed rule regarding audio-only telehealth services, APA recommends that CMS:

- Avoid imposing an in-person requirement for telehealth, either before or after the first telehealth visit, as there is no clinical evidence for an arbitrary in-person requirement before a patient can access telehealth. Since the start of the PHE, mental and behavioral health providers have successfully furnished services to patients via audio-only technology. Adding an in-person visit requirement is burdensome for current patients and will discourage new ones from seeking help. There is no scientific or clinical basis for requiring an in-person visit. As noted in the comment letter from the American Telemedicine Association (ATA), there is currently a shortage of 6,000 mental health providers in the U.S., and that shortage is expected to grow significantly worse over the next ten years. CMS will impede access to mental and behavioral health care if it imposes unnecessary requirements on coverage of telehealth services.
- Do not require additional documentation in the medical record supporting audio-only services. The documentation in the medical record already provides the information needed to justify medical necessity for the service. In addition, through the proposed use of a modifier providers will be self-certifying that they have two-way audio-visual telecommunications devices, but it is the patient who needs or wants to receive the service via audio-only. No additional documentation should be required.
- Cover high-level services such as psychotherapy for crisis furnished through audio-only telehealth. By definition, a crisis requires immediate attention as soon as possible. There should be nothing that delays or discourages a patient experiencing a crisis from having

immediate contact with a mental health provider, and audio-only telephones are the easiest and most convenient telecommunications devices available to many beneficiaries.

Traditional Telehealth Services

Last year APA and thousands of psychologists asked CMS to permanently add the psychological and neuropsychological testing evaluation codes (96130 – 96133) to Medicare's telehealth list. We also asked that testing administration codes (96136 – 96139) be added to the interim (Category 3) telehealth list, along with codes for developmental testing (96112 and 96113) and adaptive behavior & treatment (97151 – 97158, 0362T, and 0363T).

Although CMS did not adopt these recommendations, the agency now proposes to allow psychological and neuropsychological testing services to be provided through telehealth until the end of 2023. Services for developmental testing, as well as adaptive behavior and treatment, will be removed from the list of telehealth services once the PHE ends.

APA supports the proposal to allow psychological and neuropsychological testing services to remain under telehealth through 2023, as it will protect beneficiaries from suddenly losing access to critical services when the PHE ends. APA is also asking CMS to allow services for developmental testing and adaptive behavior services to continue until the end of 2023 so that patients do not lose access to critical services and to allow stakeholders additional time to demonstrate why these services should remain available through telehealth.

Multiple Family Group Psychotherapy

In our December 16, 2020, letter to CMS (Attachment B), APA asked CMS to add the code for multiple family group psychotherapy (90849) to Medicare's permanent telehealth list, even though this is not a covered service in Medicare. We are making this request to CMS again because this code's presence on the telehealth list will influence other third-party payors who look to Medicare when making coverage decisions. Even though the service will not be paid for by Medicare, having it on the telehealth list will enable psychologists and other mental health providers to be reimbursed when furnishing this service in situations that do not involve billing Medicare. Just like other psychotherapy codes, visualization of the patient and other participants is not required for the service to be appropriately furnished.

Conversion Factor Reduction

APA urges CMS to work with Congress to avoid the losses all clinicians will incur if CMS is forced to meet budget neutrality requirements. Reducing the conversion factor in 2022 as CMS is proposing will be a significant loss for many providers. Following the 3.3% loss providers incurred in 2021 – even after the additional 3.75% added by Congress that expires at the end of this year – will result in a combined reimbursement reduction of over 7% in two years. When surveyed, psychologists cite Medicare's low reimbursement rates as a primary reason for not participating in the program. Further reimbursement rate cuts will ultimately decrease Medicare patients' access to mental and behavioral health services.

Federally Qualified Health Centers / Rural Health Clinics (FQHCs / RHCs)

CMS is proposing to revise the regulatory requirement that an RHC and FQHC mental health visit must be an in-person encounter between the patient and an RHC or FQHC practitioner to also include encounters furnished through interactive, real-time telecommunications technology, but only when services are for the diagnosis, evaluation, or treatment of a mental health disorder. Under the agency's proposal, RHCs and FQHCs could furnish mental health visits using audio-only interactions

in cases where patients are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction. APA supports the proposal by CMS to allow audio-only telehealth services in RHCs and FQHCs. Medicare beneficiaries receiving services through these facilities should have the same access to mental health, substance use, and health behavior services as those being treated by providers practicing independently. Therefore, we believe the proposal should be expanded to include behavioral health services under the Health Behavior Assessment and Intervention (HBAI) codes (96158 – 96171) as well as the provision of substance use services.

Direct Supervision of "Incident To" Services

CMS has asked for stakeholder input regarding whether to allow direct supervision of "incident to" services to continue after the PHE ends. APA believes having this flexibility was enormously helpful to meet increased patient demand for mental and behavioral health services during the PHE and wishes to see it continue. As healthcare teams across the country continue to face exhaustion from increased workloads, the emphasis should remain on making the provision of care as streamlined as possible. Allowing providers to continue furnishing direct supervision via audio-visual technology increases the capacity of auxiliary staff to handle a greater patient workload, reducing wait times and allowing patients to receive care in more locations. Allowing greater beneficiary access to services is not something that should be taken away once the PHE ends.

Remote Therapeutic Monitoring

Remote Therapeutic Monitoring (RTM) services can offer providers and patients new tools to monitor non-physiologic data to help manage and adhere to a patient's therapeutic regimen, improving treatment outcomes, and saving taxpayer dollars.

CMS should adopt codes 989x1 – 989x5 for RTM so that non-physicians who cannot bill evaluation and management (E/M) services can be reimbursed for non-physiological RTM services. By adopting these codes CMS will expand the types of data obtained through remote monitoring. To ensure that patients with mental and behavioral health needs have access to these services, CMS's interpretation of therapy adherence and therapy response must go beyond medication adherence and follow the intent and cases described throughout the AMA's CPT and RUC process.

As exemplified by the real-world examples below, psychologists are among the health care professionals who provide non-physiological services through RTM and must be allowed to bill Medicare under these codes. Reimbursement rates for services under the new RTM codes should be the same as reimbursement rates for the remote physiological monitoring (RPM) codes that the RTM series was designed to resemble.

<u>Examples of Psychologists' Use of RTM Codes:</u>

<u>Initial set-up and patient education</u>

A 38-year-old female presents to the psychologist's office with moderate depression. Regular psychotherapy treatment is recommended. Following the initial visit, the psychologist initiates a remote therapeutic monitoring program to enable data collection and monitoring to support therapeutic management. The psychologist introduces the digital monitoring tool to the patient and instructs her on how to use the technology which collects and monitors treatment response (depressive symptoms and functioning) and treatment adherence (engagement in behavioral activation, use of cognitive-behavioral strategies, medication adherence, etc.).

<u>989X4 and 989X5: monitoring the actual usage & 989X5: an additional 20 minutes beyond 989X4 of monitoring time per calendar month</u>

The psychologist reviews the therapeutic monitoring data (i.e. treatment response and treatment adherence data) on the clinical dashboard. Areas that reflect deviation from expected treatment adherence, worsening of condition, or urgent need are identified. The psychologist analyzes and interprets the data. Based on the interpreted data, the psychologist uses clinical decision-making to assess the patient's condition, communicate with the patient, and oversee, coordinate, and/or modify the patient's care through shared decision making to achieve established outcomes/goals of care.

Initial set-up and patient education

A 54-year-old male with chronic back pain presents to a multidisciplinary pain management clinic and is seen by the psychologist for non-pharmacological pain management. The psychologist initiates a remote therapeutic monitoring program to review and monitor data related to signs, symptoms, and functions of therapeutic response as the patient is only seen in the multidisciplinary clinic every three months. The psychologist introduces the digital monitoring tool to the patient and instructs him on how to use the technology which collects and monitors treatment response (pain ratings, activity & functioning, sleep) and treatment adherence (use of cognitive-behavioral strategies, physical therapy, sleep hygiene, medication adherence, etc.).

989X4 and 989X5: monitoring the actual usage & 989X5: an additional 20 minutes beyond 989X4 of monitoring time per calendar month

The psychologist reviews the therapeutic monitoring data (i.e., treatment response and treatment adherence data) on the clinical dashboard. Areas that reflect deviation from expected treatment adherence, worsening of condition, or urgent need are identified. The psychologist analyzes and interprets the data. Based on the interpreted data, the psychologist uses clinical decision-making to assess the patient's condition, communicate with the patient, and oversee, coordinate, and/or modify the patient's care through shared decision making to achieve established outcomes/goals of care.

Use of RTM can be extremely beneficial in the treatment of mental and behavioral health conditions. Patients report feedback helps providers with clinical decision support and increases patient awareness of their health status, provides patients with a feeling of safety and motivation, and enables them to improve their health status (Maddison Cartledge et al. 2019).[1] In-time data collection can alert a patient to self-assess mood regularly, with data transmitted automatically to the clinician. In-time data collection is more valid, reliable, and meaningful than sporadic, retrospective reflection or recall, if the time to input data does not adversely impact patient motivation (Russell and Gajos 2020).[2]

We request the CMS clarify that medical devices with a Food and Drug Administration (FDA) product code that has been formally placed under enforcement discretion should satisfy the requirements of RPM services. Furthermore, APA requests that CMS recognize devices other than those currently contemplated for reimbursement via RTM codes. Additionally, we recognize that other devices and direct patient input tools may collect important non-physiological data on metrics such as pain, patient mood, and adherence, and their use should also be reimbursable under the CY 2022

[1] [1] Maddison, R., Cartledge, S., Rogerson, M., Goedhart, N. S., Singh, T. R., Neil, C., Phung, D., & Ball, K. (2019). Usefulness of wearable cameras as a tool to enhance chronic disease self-management: Scoping review. *JMIR mHealth and uHealth*, *7*(1), e10371]. https://doi.org/10.2196/10371

[2] Russell, M.A., & Gajos, J.M. (2020). Annual Research Review: Ecological momentary assessment studies in child psychology and psychiatry. Journal of Child Psychology and Psychiatry, 61, 376–394.

PFS. APA urges CMS to consider broader use cases for RTM, including but not limited to behavioral and mental health therapies and services addressing vascular, endocrine, neurological, and digestive systems, as was envisioned during the creation of these codes.

The use of "Software as a Medical Device (SaMD)" when used with RTM should not be categorized as an Indirect Practice Expense (PE). CMS' final rule must reflect that SaMD is not "off-the-shelf" computer software. Like medical equipment and medical supplies, SaMD is a device as defined by the FDA regardless of whether it is loaded onto and used on general purpose platforms or as dedicated ancillary medical devices. Like medical equipment, SaMD is a Direct PE, and software updates and security patches to SaMD are analogous to medical supplies (which are also Direct PEs).

APA appreciates CMS's recognition of several challenges with the new RTM codes in the proposed rule. We urge CMS to meet with the American Medical Association quickly to resolve these issues, so that disagreements regarding coding between AMA and CMS do not prevent patients from receiving services. We believe CMS should implement temporary G codes for RTM services pending resolution of outstanding issues and make these codes available for use in January 2022. In doing so, APA recommends CMS create an additional G-Code for the supply and set-up of an RTM device that parallels the condition-agnostic "supply of device" for RPM to support other acute and chronic conditions for which monitoring of therapeutic metrics and therapy adherence is useful.

Chronic Pain Management

APA appreciates CMS's consideration of new reimbursement policies for chronic pain management services. We believe current coding and payment policies do not appropriately recognize the resources involved in furnishing comprehensive multidisciplinary pain services. To capture these resource costs, APA supports the development of two new stand-alone codes rather than an add-on code to be billed with E/M services.

We think it is vitally important that two parallel comprehensive pain management codes be developed: one code for providers who can bill E/M and another code for qualified health care providers who cannot bill E/M.

CMS should not repeat the mistakes that were made with the creation of CPT code 99483. Ninety percent of the work involved in the 99483 code represents services that a neuropsychologist performs, except for the medication reconciliation or review for high-risk medications. A parallel code should have been developed to allow providers who cannot bill E/M, such as neuropsychologists, to perform this valuable service. Similarly, in the context of pain management, health psychologists play a critical role in nonpharmacological pain management and multidisciplinary care. Psychologists should be able to provide and coordinate comprehensive pain management services, except for the medication management component which is not relevant in all pain management cases. The creation of a code that only E/M providers can use will continue to place more emphasis on pharmacological management for pain and ultimately limit the number of providers engaged in providing comprehensive and nonpharmacological pain management services.

APA believes there are comprehensive pain management services that could be provided "incident to" the services of the billing physician or qualified health care provider. CMS should not restrict such billing to just the primary care provider or physician, but instead should extend this opportunity to the non-physicians, such as psychologists, who are allowed to bill for services furnished under Medicare's "incident to" provisions.

APA believes that alternative payment models (APM) are the best way to approach comprehensive pain management, and we urge CMS to form a workgroup to explore this option. We believe that an APM structure for pain management should support the increased use of nonpharmacological pain management interventions, improved coordination of care, and a prioritization of functional status outcomes and measures rather than pain ratings.[3] APA stands ready to work with CMS on developing APMs for pain management.

Lastly, CMS should take additional steps to promote comprehensive pain management services, including conducting a review of policies and allow reimbursement for services provided by multiple providers on the same day; making an exception to eliminate multiple copays for multidisciplinary care; and increasing reimbursement rates for HBAI services which are the primary codes psychologists use to provide non-pharmacological pain management services.

The Quality Payment Program (QPP)

We understand that CMS is looking at ways to promote quality and value in health care, and we support efforts that improve the quality or cost-effectiveness of mental and behavioral health care services. Unfortunately, in the QPP this has resulted in reporting programs that are constantly changing; the Physician Quality Reporting System (PQRS) turned into the Medicare Incentive-based Payment System (MIPS), which CMS now wants to turn into MIPS Value Pathways (MVP), sunsetting traditional MIPS by 2028. The constant revision of Medicare's reporting programs has left many eligible clinicians (ECs) frustrated and uncertain about their future in Medicare. ECs devote substantial time, effort, and money to accurately reporting under these systems, only to be told every few years the requirements are changing. Specialty Qualified Clinical Data Registries (QCDRs), such as APA's Mental and Behavioral Health Registry (MBHR), are working hard to develop quality measures that best reflect clinical practice and improved patient outcomes without the necessary allotment of time for provider education, implementation, and adoption due to the constant programmatic changes. As a result, many psychologists have left the Medicare program altogether, citing the struggle to find and implement measures that match their practices to avoid incurring a penalty that will decrease their already-low Medicare reimbursement. This departure threatens access to vitally important psychotherapy, testing, and integrated care services for older Americans and people with disabilities.

We ask that CMS carefully consider our recommendations about the QPP outlined below:

A. Retain the current minimum performance threshold

The minimum performance threshold based upon the mean or median of the final scores of all MIPS ECs is an unfair standard to apply to psychologists. Psychologists have few measures to choose from and are limited in their ability to report under the Promoting Interoperability (PI) category due to their exclusion from federal incentive payments for the "meaningful use" of electronic health records technology. This leaves psychologists with far fewer opportunities to amass points compared to ECs in other specialties.

We are asking CMS to retain the current minimum performance threshold of 60 points for MIPS reporting, and not adopt its proposal to raise the number to 75. Given the barriers cited above, it will be extremely difficult for psychologists to increase their number of points by 25% in just one year to avoid a 9% penalty.

[3] https://acoem.org/acoem/media/PDF-Library/Publications/Recommendations_From_the_2019_Symposium_on-26-(1).pdf

B. Retain bonus points for high priority measures

CMS should continue to provide bonus points for reporting outcome/patient experience measures and high priority measures beyond the mandatory one point. Removing the opportunity to receive bonus points while the agency proposes to raise the current minimum performance threshold increases the risk that many ECs will face a penalty rather than securing a neutral or positive payment adjustment. Additionally, outcome/patient experience measures and high priority measures are generally in the best interest of the patient in terms of quality care and should be encouraged and rewarded with bonus points. Retaining bonus points also align with CMS's stated goal to move away from reporting process measures and prioritizing the reporting of outcomes. Process-focused reporting is often more difficult for psychologists to implement due to barriers related to workflow burden, compounded by the omission of support for psychologists' adoption and use of EHRs.

C. Quality Measure Scoring

We strongly support establishing a 5-point floor for quality measure scoring for the first 2 performance periods for new measures submitted that meet the data completeness requirement, under the assumption that this includes QCDR measures. We recommend that this 5-point floor be retroactive for measures introduced in 2020 and 2021, and that measures introduced in performance year 2020 have an additional performance year (PY 2022) due to the "extreme and uncontrollable circumstances" policies in effect for PY 2020. New measure adoption can be a challenging process due to workflow and documentation barriers, and uncertainty around benchmarks often deter providers from choosing new measures despite the measure's specialty relevance and likelihood to result in improved quality of care.

We support retaining the 3-point floor for small practices, and also recommend retaining the 3-point floor for any measures without a benchmark that were introduced during PY 2020 due to the "extreme and uncontrollable circumstances" policies in effect for that reporting period.

D. Improvement Activities

We support the addition of new Improvement Activities designed to promote health equity and clinician well-being.

E. Promoting Interoperability (PI)

We request clarification regarding the proposal by CMS to automatically reweight the PI category for clinical social workers and ECs in small practices. We are asking CMS to confirm that psychologists and certain other non-physician ECs will continue to have the PI category reweighted to zero given that, as noted above, they never received federal assistance in adopting EHR systems. It is critical that all psychologists, including those in practices with more than 15 ECs, continue to have the PI category reweighted to zero unless they choose to report PI measures or are provided with federal funding to invest in EHR.

We also request that CMS implement Section 6001 of the SUPPORT Act (PL 115-271), which authorized the Centers for Medicare & Medicaid Services Innovation Center (CMMI) to test models for providing incentive payments to behavioral health providers to promote the adoption and use of certified EHR technology to improve care coordination and quality.[1]

F. The transition from MIPS to MIPS Value Pathways

We appreciate the desire by CMS to address providers' concerns regarding quality payment reporting burden. MIPS Value Pathways, which are core measure sets, may address this burden,

but are only likely to be feasibly developed for certain settings, such as long-term care, or for certain subspecialty providers, such as neuropsychologists. MVPs are not likely to be feasibly implemented for psychologists in generalist practices who see between 30 – 40 patients per week, presenting with various different diagnoses (e.g., depression, anxiety, PTSD, psychosis, etc.), and including patients across the lifespan. One core measure set, or MVP, would not be able to account for the level of heterogeneity of patients whom a generalist psychologist provides treatment, and having to implement multiple different MVPs would increase the burden that ECs currently experience with traditional MIPS. One solution would be to retain traditional MIPS for those providers for whom no MVPs are relevant or are not feasibly able to be implemented and instead reduce the number of quality measures reported from 6 to 4 to better align with MVPs. This would reduce reporting burdens, while giving providers better options to select the measures that are most meaningful to their particular patient population.

As noted above, psychologists and certain other non-physician ECs remain at a severe disadvantage regarding the use of EHRs. It was for this reason that CMS has been reweighting the PI category to zero for their reporting under MIPS. With the MVP program approach of using the PI category as a foundation to promote moving to digital quality measures, psychologists are at high risk of failure, risking both a loss in reimbursement and an inaccurate perception of not delivering quality services. We fear that too many psychologists will find the new MVP requirements increasingly burdensome, further disincentivizing their participation in Medicare.

We are also concerned that the timeline for moving ECs from MIPS to MVP does not allow specialties enough time to develop relevant MVP models. Currently, there are no model MVPs that psychologists could use, and given the challenges described above the prospects for developing MVPs that work for all psychologists by 2023 is daunting, if not impossible as outlined above. Further, there are currently no-cost measures for mental and behavioral health, again a foundational component of MVPs, and those that have been developed to date were rejected. Additionally, this transition places an excess burden on qualified clinical data registries (QCDRs) to be ready for MVP reporting by 2023. The timelines for both the self-nomination process and the publication of the final rule and approved QCDR measures leave precious little time for vendors to implement and prepare for traditional MIPS as it stands. Adding MVP reporting into the mix will only complicate an already difficult preparation process.

APA wants to thank CMS for this opportunity to provide comments on the proposed rule involving changes to payment policy under the 2022 Medicare physician fee schedule. If your staff have any questions, you are welcome to contact our Director of Regulatory Affairs, Diane M. Pedulla, J.D., by telephone (202-336-5912) or email (dpedulla@apa.org).

Cordially,

Arthur C. Evans, Jr., PhD
Chief Executive Officer /
Executive Vice President
American Psychological Association Services, Inc.

Stephen R. Gillaspy, PhD
Senior Director,
Health & Health Care Financing
American Psychological Association Services, Inc.

AMERICAN PSYCHOLOGICAL ASSOCIATION
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December 16, 2020

Division of Practitioner Services Mail
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Security Boulevard
Baltimore, Maryland 21244-1850

Attention: Telehealth Review Process

To Whom It May Concern,

On behalf of American Psychological Association (APA), the largest scientific and professional organization representing psychology in the United States, with nearly 121,000 researchers, educators, clinicians, consultants and students, we are writing to you today to request the addition of the following four (4) CPT® codes to the list of Medicare telehealth services. The APA believes that psychological and neuropsychological testing evaluation services meet the Category 1 criteria and are similar to the existing psychotherapy services on the list of telehealth services, including CPT codes 90832, 90833, 90834, 90836, 90837, and 90839. The codes include the base/add-on code pairs that describe psychological and neuropsychological testing evaluation services:

- 96130; *Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour*
    - + 96131; *Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)*
- 96132; *Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour*
    - + 96133; *Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)*

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The family of psychological and neuropsychological testing codes were reviewed and revised by the AMA/Specialty Society RVS Update Committee (AMA RUC) in April 2019, and the new CMS-approved code set went into effect on January 1, 2019. Current Medicare utilization data shows that this service is typically performed by Clinical Psychologists, Neuropsychologists, Psychiatrists, and Neurologists.

The APA believes that psychological and neuropsychological testing evaluation services should be added to the definition of Medicare telehealth due to the interactive feedback session component of the service. A post-evaluation interactive feedback session with the patient and/or family members is a typical part of the neuropsychological and psychological evaluation (*American Psychological Association, 2017*; *Finn, 1996*; *Pegg et al., 2008*; *Postal & Armstrong, 2013*). It is empirically shown to produce clinically meaningful benefits (*Poston & Hanson, 2010*) including symptomatic, quality of life, social adjustment improvements (*Miller, Cano, & Wurm, 2013*; *Smith, Eichler, Norman, & Smith, 2015*), better ability to cope with their condition (*Rosado et al., 2018*), decreased healthcare utilization (*Janecek et al., 2018*) and receiving test results is highly valued, not only by patients *(Westervelt, Brown, Tremont, Javorsky, & Stern, 2007*), but also physicians who refer their patients for neuropsychological assessments (*Postal et al, 2017*).

The interactive feedback session typically emphasizes any or all of the following:

- Discussion of the relationship between test results and information about diagnosis and prognosis.
- Patient education about their diagnosed condition and functioning with the goal of improving adherence to treatment plans, and safety.
- Explanation of treatment recommendations. In addition to those recommendations that are directly managed by the patient's medical provider (e.g., changes in medication or treatment), patients are provided with evidence-based treatment recommendations that are not typically managed by medical providers, and which are best explained by providers with expertise in neuropsychological or psychological assessment, including tailored behavioral strategies to maximize functioning, safety measures such as driving recommendations, referrals to other specialty providers (e.g., psychiatry, rehabilitative therapists), recommendations for nonpharmacological interventions, and community resources that assist in optimizing treatment and prognosis.
- Communication of results in the presence of family members in order to explain treatment recommendations, which enhances treatment outcome for the patient (*Postal, 2018*), and – for patients with dementia – may result in up to an 18-month delay in nursing home placement when caregivers are provided with education and connected to caregiver resources (*Mittelman, et al. 2006*). In some cases, a patient may be undergoing treatment or may be too cognitively impaired to engage in feedback. In such circumstances where the physician or QHP determines that feedback is necessary to ensure adherence to treatment plans including safety issues, feedback may be given to the patient's caregiver (with appropriate permissions and release of information).

The interactive feedback session is a unique service, provided only as part of psychological and neuropsychological testing evaluation services. While the feedback session is delivered in a similar fashion, it is not typically a psychotherapy service; therefore, the CPT codes that describe psychotherapy services (i.e. 90832, 90833, 90834, 90836, 90837, and 90839), which are currently on the list of Medicare telehealth services, would not be appropriate for billing the service requested.

We thank you in advance for your consideration of our request for addition of CPT codes 96130, 96131,96132 and 96133 to the list of Medicare telehealth services based on proper coding methodologies associated with

these services. Should you have questions or require additional information, please contact APA's Coding and Payment Policy Officer, Meghann Dugan- Haas, by telephone at 540-230-3624 or by email at mdugan-haas@apa.org.

Sincerely,

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Sources of Information

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AMERICAN PSYCHOLOGICAL ASSOCIATION
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December 16, 2020

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Attention: Telehealth Review Process

To Whom It May Concern,

On behalf of American Psychological Association (APA), the largest scientific and professional organization representing psychology in the United States, with nearly 121,000 researchers, educators, clinicians, consultants and students, we are writing to you today to request the addition of the CPT® code 90849; *Multiple-family group psychotherapy*, to the list of Medicare telehealth services. The APA believes this service meets the Category 1 criteria, as it is similar to CPT code 90853; *Group Psychotherapy*, an existing code on the list of telehealth services.

During family psychotherapy services, the emphasis is on the patient's care, with therapy aimed at the milieu environment in which the patient lives or will live and the interactions of the particular family-based milieu situation. CPT code 90849 is reported when multiple family members and/or caregivers and the identified patients meet to share experiences, give and receive support, acquire insight, and develop new ways of coping or behaving. The service is performed under the direction of a clinician, who fosters therapeutic interaction and maintains a safe and supportive environment for patients being treated.

The multiple-family service is similar to group psychotherapy (code 90853) except, instead of just patients present in the group setting, family members and/or caregivers of the patient are also present and part of the treatment. The inclusion of the family member(s)/caregiver(s) is critically important, particularly in the treatment of children, adolescents and some adults such as those with developmental disabilities and/or early dementia. Similar to group psychotherapy, multi-family group therapy enhances the effectiveness of therapy by exposing patients to others who are experiencing similar conditions and building support across patients to practice the therapeutic skills taught in treatment in their daily lives. The inclusion of family member(s)/caregiver(s) in the identified patient's group therapy, enhances the psychotherapeutic effectiveness in several ways, including, but not limited to:

1) The family member(s)/caregiver(s) can support the patient in incorporating and practicing the therapeutic intervention in their daily lives, which is necessary for and consistent with evidence-based interventions for many pediatric behavioral health concerns;
2) The group setting can also support the family member(s)/caregiver(s) in better managing the patient's symptoms and psychological condition through the support of others in similar situations, which is critical for ongoing family engagement in treatment. This type of support can be especially critical in the treatment of children, adolescents and adults with developmental disabilities where family member(s)/caregiver(s) play a

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crucial role in structuring the patients' environment and encouraging use of the therapeutic skills in daily life;
3) Provides family member(s)/caregiver(s) with psychoeducation about the patient's disorder and adaptive approaches to help the patient manage their symptoms, thereby maximizing family resources and support to the patients. In some studies, multi-family group psychotherapy has been found to be equally effective in treating anorexia nervosa as individual family therapy (*Eisler et al., 2016*); and
4) Increasing mental health services for patients and families/caregivers by increasing treatment capacity and delivering care at a lower cost than individual treatment.

According to current Medicare utilization data, the types of medical professionals that typically provide this service include Clinical Psychologists, Licensed Clinical Social Workers, Psychiatrists or other licensed therapists.

The APA believes that the multi-family group psychotherapy should be added to the list of Medicare telehealth services due to it being empirically shown to be produce clinically meaningful benefits including reductions in symptoms, increased quality of life, social adjustment improvements and better ability to cope with their condition across conditions of: mood disorders (*Fristad et al., 2003*; *MacPherson, Mackinaw-Koons, Leffler, & Fristad, 2016*; *Sherman et al., 2015*); schizophrenia (*McFarlane et. al., 2003*); anorexia nervosa (*Eisler et al., 2016*); conduct disorders (*Morris et al., 2014*); bipolar disorder (*Colom et al., 2009*; *Milklowitz, 2003*); and autism spectrum disorders (*Smith, Greenberg, & Mailick, 2012*).

The multi-family group psychotherapy typically emphasizes:

- Patient and family member/caregiver education about the patient's diagnosed condition and evidence-based intervention with the goal of improving adherence to treatment plans, and safety.
- Explanation of treatment recommendations including tailored behavioral strategies to maximize functioning, safety measures, recommendations for nonpharmacological interventions, and community resources that assist in optimizing treatment and prognosis.
- Communication of treatment recommendations in the presence of the patient's family member(s)/caregiver(s) in order to enhance treatment outcomes for the patient.

We thank you in advance for your consideration of our request for addition of CPT code 90849 to the list of Medicare telehealth services. Should you have questions or require additional information, please contact APA's Coding and Payment Policy Officer, Meghann Dugan- Haas, by telephone at 540-230-3624 or by email at mdugan-haas@apa.org.

Sincerely,

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Sources of Information

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September 10, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: [CMS-1751-P] Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements

Dear Administrator Brooks-LaSure,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Fiscal Year (FY) 2022 Physician Fee Schedule (PFS) Proposed Rule. Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,500 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other surgical procedures within the chest.

Contents *(taken out of order)*

VII. Regulatory Impact Analysis

CMS estimates the CY 2022 PFS conversion factor (CF) to be $33.5848, which reflects the budget neutrality adjustment (i.e., -0.14) and the 0.00 percent update adjustment factor. It also accounts for the expiration of the 3.75 percent increase provided for CY 2021 under the *Consolidated Appropriations Act, 2021* (CAA). These changes plus the impact of other policies proposed by the Agency amounts to an approximately -5% adjustment for cardiothoracic surgeons in CY 2022 as the country continues to battle public health emergencies and health care financing crises due to ongoing COVID-19 surges and emerging variants.

What's more, the 5% cut is not the total financial negative impact since it does not include the agency's continuing refusal to update global surgical service Evaluation & Management (E/M) values commensurate with increases to stand-alone E/M visits implemented last year. Although those changes are not included in this year's impact table, their impact will be felt again this year. Further discussion about the E/M visits included in the global period is included below.

Finally, CMS' impact table does not include estimates of the impacts of statutorily mandated sequestration. Figure 1a and 1b depict two of the most common codes billed by cardiothoracic surgeons, coronary artery bypass graft (CABG) and lung open lobectomy and their respective decrease over time, both in real dollars and dollars adjusted for inflation. The last data point in each chart estimates the impact of the proposed 2022 PFS conversion factor cuts, net adjustments for the consolidated appropriations act reduction, decreased reimbursement for the global surgical period E/Ms, and pending sequestration cuts.

Figure 1a

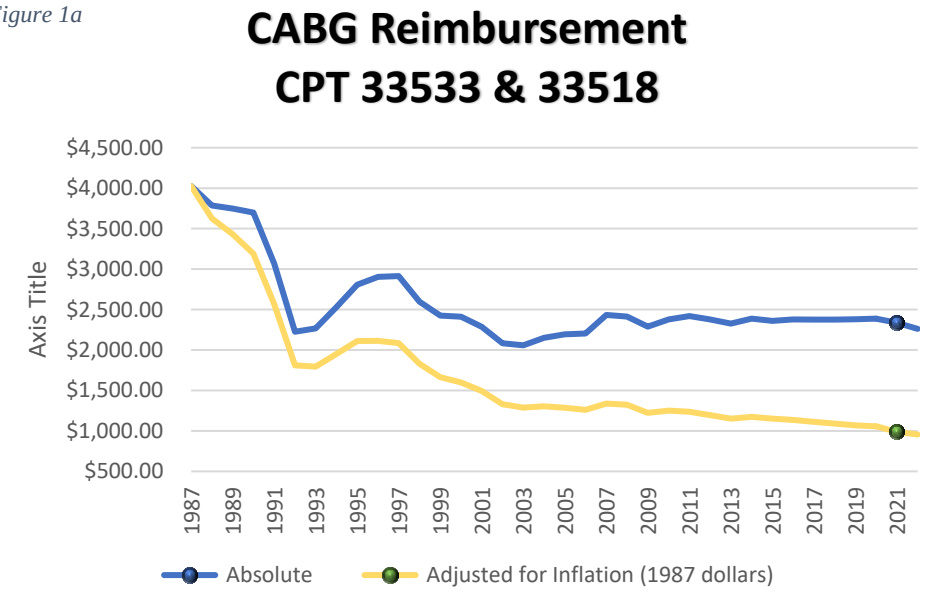
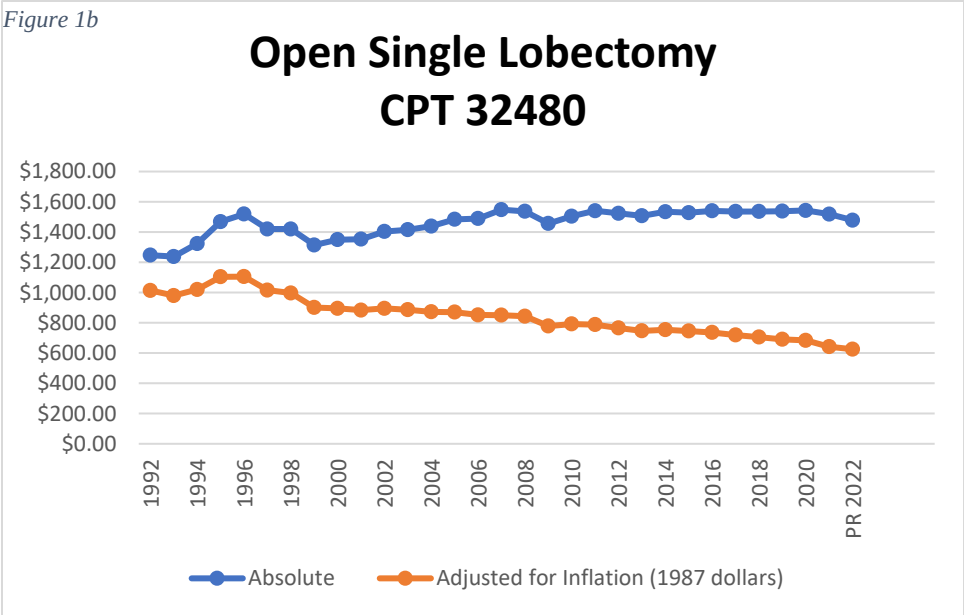


Figure 1b



As mentioned above, it is inappropriate for CMS to apply the RUC-recommended changes to stand-alone, in-office E/M visits but not for E/M services that are imbedded within global surgical codes. CMS' persistence in this policy for yet another year:

- Disrupts the relativity in the fee schedule: CMS is arbitrarily changing the values for some E/M office visit services, but not others, disrupting the relativity between codes across the Medicare physician fee schedule. This relativity was mandated by Congress, established in 1992, and has been refined over the past 27 years. Historically (1997, 2003 and 2011), CMS itself has ensured this relativity between office/outpatient E/Ms and those associated with global surgical codes

by increasing the value to global services commensurate with, and identical to, increases in office / outpatient E/M because of the direct relationship between the codes in the significant revaluations of office/outpatient E/Ms.

- Creates specialty differentials: Per the Medicare statute, the "Secretary may not vary the…number of relative value units for a physicians' service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician."[1] Failing to adjust the global codes is tantamount to paying some doctors less for providing the same E/M services, in violation of the law. CMS's ongoing non-compliance with the law is disturbing, and we ask by whose authority are they able to remain non-compliant for yet another year.

- Ignores recommendations endorsed by nearly all medical specialties: The RUC, which represents the entire medical profession, voted overwhelmingly (27-1) to recommend that the full increase of work and physician time for office visits be incorporated into the post-operative visits of the global surgery codes for each CPT code with a global period of 10-day, 90-day and maternity codes. The RUC also recommends that the practice expense inputs should be modified for the office visits within the global periods.

- Inappropriately relies on section 523(a) of MACRA: In the CY 2021 PFS proposed rule, CMS refers to its decision in the CY 2020 PFS final rule to not make changes to the valuation of the 10- and 90-day global surgical packages to reflect the increased values for the office/outpatient E/M visit codes while the agency continues to collect data on the number and level of post-operative visits included in global codes as required by MACRA. The MACRA data collection requirement, set forth in section 523(a), does not prohibit CMS from applying the RUC-recommended incremental increases to the office/outpatient E/M codes to global codes. In fact, section 523(a) specifically authorizes CMS to adjust surgical services, notwithstanding the mandate to concomitantly undertake the MACRA-mandated global code data collection project. In addition, it is inappropriate for CMS to rely on the implementation of MACRA, which passed in 2015, as a reason to refrain from making necessary updates. CMS continues to make and/or defer policy decisions, such as their proposal to bundle critical care visits with procedure codes that have a global surgical package in Section II (F)(2)(g) of this proposed rule, under the premise of continued assessment of values for global surgery procedures including the number and level of pre and postoperative visits. CMS is arbitrarily making or deferring changes to code valuations and policy in a manner that suites their needs as opposed to applying the guidance in a consistent manner.

The agency's flawed decision to use the MACRA statute to continue to stall in implementing a change to global reimbursement, unfairly punishes a subset of physicians. CMS' failure to incorporate RUC-recommended work and time incremental increases for the revised office/outpatient visit E/M codes in the global codes is unacceptable, particularly considering the adjustments proposed for other bundled services, such as the maternity codes. CMS further penalizes surgeons in the *Proposed Valuation of Specific Codes for CY 2022* section (II)(E)(4) of this rule for procedures where the global periods are changing from 90-day or 10-day global periods to 0-day global periods. One example appears to occur where CMS utilizes a reverse building block methodology (BBM) using the new 2021 E/M values and

[1] 42 U.S. Code §1395w-4(c)(6)

time to determine a work RVU even though the 2021 increases were not included in the E/M codes that are included in the global surgical package; furthermore, the codes were valued using magnitude estimation. Using a reverse building block methodology (BBM) with 2021 E/M office visit code values on codes that were valued using magnitude estimation is inappropriate resulting in additional unsubstantiated decreases in surgical procedure work valuations. CMS could easily address this disparity by increasing the visits bundled into the surgical global payment which would increase spending by approximately $440 million, requiring an approximate 0.4% reduction to the Medicare conversion factor. This is a minor budget neutrality impact in comparison to the impacts proposed for the increases to the stand-alone office visits and other CMS proposals. Organized medicine has been united in its recommendations that CMS incorporate the incremental revised office/outpatient E/M values in the global codes, as evidenced by the many comment letters and meetings over the past year.

II. Provisions of the Proposed Rule for the PFS

B. Determination of Practice Expense (PE) RVUs

Anticipated Specialty Assignment for Low Volume Services Code List

STS appreciates CMS' policy to use expected specialty service-level overrides for both practice expense (PE) and malpractice (MP) for certain low volume services. Application of the specialty overrides for low volume services ensures that the expected indirect practice expense is appropriately represented. The policy also ensures that the malpractice risk inherent to a code is reflected in the malpractice risk of a singularly qualified specialty. Specialty assignments to these low volume codes avoids major adverse impact on professional liability insurance (PLI) relative value units (RVUs) that result from errors in specialty utilization data that is magnified by small sample size such as congenital cardiac surgery.

The *Anticipated Specialty Assignment for Low Volume Services* list, which is included in the CMS annual data files, includes a column specifying if a service that had previously had an anticipated specialty override continues to meet the criteria for the override to be applied for CY 2022. The RUC performed an analysis to identify all codes that meet the criteria to receive a specialty override under the CMS policy for CY 2022. STS worked with the RUC's PLI Workgroup to review this information. The list of codes provided in Appendix A of this comment letter was developed with the purpose of assigning the appropriate override specialty to these low-volume codes to avoid the major adverse impact on the PLI RVUs that result from errors in specialty utilization data magnified by small sample size. STS has commented on this issue for years. However, each year CMS has incorrectly assigned congenital cardiac services to the wrong specialty (e.g., thoracic surgery). These errors often have a significant, deleterious impact on congenital cardiac surgeons because the true code utilization relates to non-Medicare beneficiaries: children.

STS has also included a list of codes in which thoracic surgery or another specialty is currently the expected specialty assignment. STS recommends different and more appropriate specialty assignments for these codes. The STS specialty crosswalk recommendations for changing the override specialty from thoracic surgery to cardiac surgery is based on the concept that codes that are considered "cardiac" in nature, i.e., those procedures performed on the heart and surrounding structures, should be designated with the override specialty of "Cardiac Surgery" and that codes that are considered "Thoracic Surgery", i.e., procedures performed on the lungs, esophagus, chest wall and mediastinum, should be designated with the override specialty of "Thoracic Surgery." For these reasons, STS is recommending that the

override specialty for a significant number of the low-volume cardiothoracic surgery codes in the list, many of which represent congenital cardiac procedures, be changed to cardiac surgery.

CMS correctly assigned several of these services to Cardiac Surgery after our comments in 2019. However, in CY 2020, CMS again reassigned them back to Thoracic Surgery. The Society and the RUC have provided information on the expected specialty for these codes when the expected specialty list was developed and have been consistent in our comments over the past several years as to the correct specialty assignments for these codes. We once again ask that CMS ***permanently*** assign the codes listed in Appendix A of this letter to the indicated specialty to avoid any adverse impacts on the PE and/or MP RVUs for these codes.

While the malpractice risk factor for both cardiac surgery (6.37) and general thoracic surgery (6.45) is naturally very similar, we are still unclear as to why the thoracic malpractice risk factor is slightly higher than the cardiac surgery malpractice risk factor. STS requests that CMS work with the Society and the RUC to identify the reason for this discrepancy in the cardiac and thoracic surgery malpractice risk factors and correct it so that the cardiac and thoracic surgery low-volume codes reflect the appropriate override specialty and malpractice risk factor.

STS commends CMS on their continued efforts to ensure that the list of expected specialties is correctly and consistently applied for the low volume service-level overrides each year. Appendix A lists a number of low volume codes to be added, reactivated or assigned a different specialty. STS strongly recommends that CMS incorporate the list of codes included in Appendix A to the CMS anticipated specialty assignment for low volume services.

d. Clinical Labor Pricing Update

CMS proposes to update clinical labor pricing for CY 2022 using the 2019 Bureau of Labor Statistics (BLS) survey data noting that the potential effects of the clinical labor pricing update on specialty payment impacts are largely driven by the share that labor costs represent of the direct PE inputs for each specialty. Therefore, specialties with a substantially lower or higher than average share of direct costs attributable to labor would experience significant declines or increases, respectively. CMS also explains that it is considering whether it would be appropriate to implement the clinical labor pricing updates through a 4-year transition to smooth out the increases and decreases in payment caused by the pricing update for affected stakeholders. CMS proposes to update the clinical labor pricing for CY 2022 in conjunction with the final year of the supply and equipment pricing update.

PE within the PFS is a fixed pool of resources. Increasing clinical labor (CL) payments redistributes funds from supplies and equipment, directing a larger portion of the PE pool towards clinical labor. Under this proposal, the direct practice expense (PE) pool increases by 30 percent resulting in a significant budget neutrality adjustment. The proposed update results in a 24.4% decrease in the PE direct scaling factor for CY 2022. The specialty-level impacts of increasing clinical labor pricing illustrate that physician services with high-cost supplies and equipment are particularly harmed by the budget neutrality component within the PE relative values.

STS along with ACS, AMA and numerous other medical societies recommend that CMS “fix” the problem related to high-cost supplies by establishing Healthcare Common Procedure Coding System (HCPCS)

Level II codes for supplies that exceed $500. Limb-saving interventions provided in an office have kept many patients out of the hospital setting and away from COVID-19 patients during the Public Health Emergency (PHE). This cost inhibiting update will be higher than the office's income stream can justify, limiting providers' ability to perform these services in the office and forcing them to send their patients to facilities where patient-care resources are already strained due to the PHE. We strongly urge CMS to address this problem and establish HCPCS Level II codes for all supply items that exceed $500.

CMS states that the clinical labor (CL) rates were last updated in CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources where BLS data were not available. Each of the examples of other sources represent data that are not readily available for public review to determine if the same process of collection is used. For CY 2022, 14 (44%) of the 32 single staff types are being updated using a BLS crosswalk because an exact match was not available. CMS is soliciting comments on the proposed updated CL pricing as well as methods to identify the most accurate types of BLS categories that could be used as proxies to update pricing for CL types that lack direct BLS wage data. The Agency is also interested in additional wage data that may be available. STS does not have any specific recommendations for specific resources as proxies for CL types that are not in the BLS wage data, but we encourage CMS to consider comments from the specialty societies and other entities on specific clinical staff types and their labor rate costs.

To account for employers' cost of providing fringe benefits, such as sick leave, CMS proposes to use the same benefits multiplier of 1.366 that was utilized in CY 2002. We disagree with this proposal as this multiplier is not accurate according to current BLS data. The most recent news release bulletin for "Employer Costs for Employee Compensation" indicates that the private industry worker's median and mean benefit cost was 29.6 percent. We believe that the private industry worker's rate is appropriate as it eliminates overemphasis on non-healthcare wages, such as those for farmers and federal employees. We recommend that CMS use the current fringe benefit multiplier of 1.296 in the calculation to update CL rates.

CMS also indicates that when updates to a payment methodology based on new data produce significant shifts in physician reimbursement, the Agency often considers whether it would be appropriate to implement the updates through a phased transition across several calendar years. For several reasons, we agree that it would be most equitable for the proposed CL rate update to be phased-in over four years, and in addition, we strongly urge the Agency to delay implementation of the update until CY 2023 after the final transition year of the supply and equipment update.

There are several specialties that will be disproportionately impacted by both the CL rate update (due to the embedded high-priced supply items) and the final transition year of repricing supplies and equipment. For example, the real impact on vascular surgeons is estimated to be a decrease of almost 12% based on a 4% decrease due to changes in clinical labor, a 4% decrease due to changes in supply and equipment pricing and the scheduled expiration of the one-year 3.75% increase provided by the CAA for CY 2021. This percentage is significantly greater (-20%) for those providers that perform the limb-saving procedures that include high-cost supplies and equipment. We believe that a -20% decrease in reimbursement in one year will result in practices going out of business and many providers leaving the profession, which will ultimately impact patients' access to timely care.

Delaying implementation of the CL rate update for one year, allows stakeholders more time to respond to the proposed update that decreases the direct PE scaling factor in the PE calculation by -25% and the Agency's request for additional information about other wage price data.

STS also encourages CMS to update pricing data on a more frequent basis for all inputs, to minimize the impact on adjustments in the future. While STS has concerns with the impact of the CL rate increases, we also recognize the need to have current wage data to ensure appropriate reimbursement for direct PE costs. The rising costs of nursing and the escalating shortages of this labor force is one example of the significant impact that direct labor costs have on a practice. The increased costs are real and are passed on to physician practices. Increasing the CL costs to reflect current rates in the direct PE inputs is essential to ensure that physicians are appropriately compensated for these incurred costs. These increased costs should not be subject to budget neutrality adjustments. There is an underlying unfairness that the real increase in clinical labor costs is not recognized through an update to the conversion factor and we call on CMS to urge Congress to provide a positive update to the Medicare conversion factor in 2022 and all future years.

D. Telehealth and Other Services Involving Communications Technology

CMS proposes to retain all Category 3 services on the Medicare telehealth services list until the end of 2023. This category describes services that were added during the PHE for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition under Category 1 (similar to existing Medicare benefits) or Category 2 (need to demonstrate clinical benefit to Medicare patient). CMS asks if any of the services in Table 11, which were added to the Medicare telehealth services list on an interim basis in response to COVID-19, but that were not extended on a temporary Category 3 basis, should now be added to the Medicare telehealth services list on a Category 3 basis to allow for additional data collection and submission to CMS. CMS also asks if any other services should be added to the Medicare telehealth services list on a Category 3 basis.

STS supports CMS' proposal to retain all Category 3 Services on the Medicare telehealth services list until the end of 2023. STS also encourages CMS to add the services listed in Table 11 to the Medicare telehealth services list on a Category 3 basis through 2023 to allow stakeholders time to collect additional clinical data that supports their addition on a permanent basis. While STS agrees that all of the codes in Table 11 should be included in the list of services that remain on the telehealth list through 2023, we particularly support adding the VAD interrogation code (93750), the hospital inpatient services codes (99221 – 99223), the observation care services codes (99218-99220 and 99234-99236), the telephone evaluation and management services codes (99441-99443) and the critical care services codes (99468, 99471, 99473, 99475 and 99477) to the list. STS continues to believe that this is an important step in establishing a pathway for telehealth services that have demonstrated clear clinical benefit to remain covered even after the COVID-19 PHE concludes. The Society suggests considering the following evidence as part of category 3 clinical assessment of services:

- Decrease in ED admissions
- Decrease in readmissions
- Improved access for underserved populations and patients, including rural locales
- Increase in patient satisfaction

We remain confident that data collected during COVID-19 will demonstrate the positive impact telehealth has had on both patient clinical outcomes and patient experiences. As we have previously stated, there are some data to support that telehealth services play an important role in decreasing readmissions and emergency department treatments and providing rural patients with access to otherwise limited resources. Some VA studies have shown high patient satisfaction with telehealth services and no increase in mortality. Advances in technology and the advent of more sophisticated equipment has increased the extent of patient monitoring via telemedicine and has resulted in increased physician and patient satisfaction. Anecdotally, many patients have reported to STS members that these services have enabled patients to feel more connected to their provider and engaged in the health care experience. Although this is likely true for all patients, we recommend CMS continue to broaden the scope of telehealth services coverage and reimbursement and particularly consider impacts to traditionally underserved patient populations and geographic locations.

While STS supports some provision of continued payment for audio-only visits in appropriate circumstances, we do not believe that audio-only is adequate for more complex visits. We acknowledge that use of audio-only visits during the COVID-19 PHE has demonstrated a legitimate benefit and as such continue to support maintaining these services on the telehealth services list through 2023 while data is collected to determine which visits are suitable for audio-only and establish an appropriate payment rate. Suitable visits will likely be less complex than in-person visits and video visits and therefore compensation would not be at the same rate. STS recommends that any audio-only services be sent through the valuation process to ensure that they are appropriately valued.

STS also supports permanently extending the option for virtual supervision when clinically appropriate. Although clinical circumstances, supervisee experience-level, and type of supervisee (resident or different non-physician practitioner types) should influence the extent to which virtual supervision is appropriate, STS recognizes the benefits of continued virtual supervision. Virtual supervision continues to be effective and efficient in many clinical settings with both residents and non-physician practitioners. However, STS does suggest that after the COVID-19 PHE, video may be necessary in some, but not all, supervising roles. STS recommends that CMS make permanent the interim allowance for virtual supervision even after the conclusion of the COVID-19 PHE.

E. Valuation of Specific Codes

STS supports CMS' proposal to accept the RUC recommended work value for the percutaneous insertion and removal of cerebral embolic protection devices (CPT codes 33XXX). This new technology is important to increasing patient safety for certain cardiac procedures such as TAVR. STS also supports CMS' decision to accept the RUC recommended work and PE values for Exclusion of Left Atrial Appendage (CPT Codes 33XX3, 33XX4, and 33XX5). These services will provide patients with additional treatment options for this indication.

CMS states that it remains a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations and that they work with stakeholders, including the RUC with regard to its approach for accurately valuing codes, and will continue to welcome feedback from all interested parties. CMS goes on to explain that "with regard to work RVUs, many stakeholders, namely the American Medical Association (AMA) Relative Value System Update Committee (RUC) and various specialty societies, have expressed

concerns over the years with its ongoing adjustment of work RVUs." CMS highlights that it "does not ignore the AMA RUC-recommended work RVUs; rather, it uses them as starting point in making refinements using various methodologies and data derived from the AMA RUC survey process."

STS continues to have significant concerns with the various methodologies that CMS uses in refining the survey-based data and agreed upon work RVU valuation recommendations from the AMA RUC and the representative specialty societies. STS, along with other stakeholders have commented several times in the past that CMS is overlooking the intensity component and its role in valuation of the procedures. Section II (A)(1)(a) of this rule regarding the development of work RVUs states: "*As specified in section 1848(c)(1)(A) of the Act, the work component of physicians' services means the portion of the resources used in furnishing the service that reflects physician time and **intensity** [emphasis added]*." Section1848(c)(2)(C)(i) of the Act further specifies that ''*the Secretary shall determine a number of work relative value units (RVUs) for the service based on the relative resources incorporating physician time and **intensity** [emphasis added] required in furnishing the service*.'' In Section II (E)(2) of the proposed rule, CMS goes on to state *"We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs."*

Despite these claims, CMS continues to ignore the intensity of services evaluating them solely on the time it takes to perform the procedure, or some other strategy designed to support their recommendations to almost always decrease the RUC recommended work values. CMS' failure to recognize intensity in valuing physician work goes against their statutory directive and creates inherent payment disparities in the relativity of valuations in the payment system. The current fee schedule is based on magnitude estimation and there are subtle differences in each procedure that can lead to variations in how specific codes are valued. The intensity of a procedure is characterized by added technical skill, physical and mental effort, and additional judgment and stress, all of which should be considered in addition to the time associated with procedures. For example, with the expansion of more catheter-based options over more traditional open surgical procedures, there is compelling evidence that the more traditional surgical procedures are being performed on an evolving population of sicker, higher acuity patients. As a result, the issue of intensity is becoming a much more relevant factor for cardiothoracic procedures.

STS also has concerns with CMS using a reverse BBM to adjust time and work values for codes that are valued using magnitude estimation as they have proposed to do for some codes (e.g., those going from 90-day to 10-day or 0-day global periods) in this rule. It is inappropriate for CMS to use a reverse BBM, to back out the associated time and values of the E/M codes included in the global surgical package because the codes were not valued using a BBM in the first place. Application of a reverse BBM to adjust code values that were valued using magnitude estimation inappropriately reduces the final values. By using the new and increased 2021 E/M times and values in their reverse BBM to determine new work RVUs, CMS further devalues the physician work associated with the procedure since the increased value from the 2021 E/M codes was not passed through to the E/M codes included in the global surgical package. We are clearly bewildered by CMS' action here. They feel it inappropriate to carry the new 2021 E/M valuations into the global period E/M codes, yet they feel it appropriate to back out the 2021 increased valuations even though those valuations were never part of those codes. In addition to

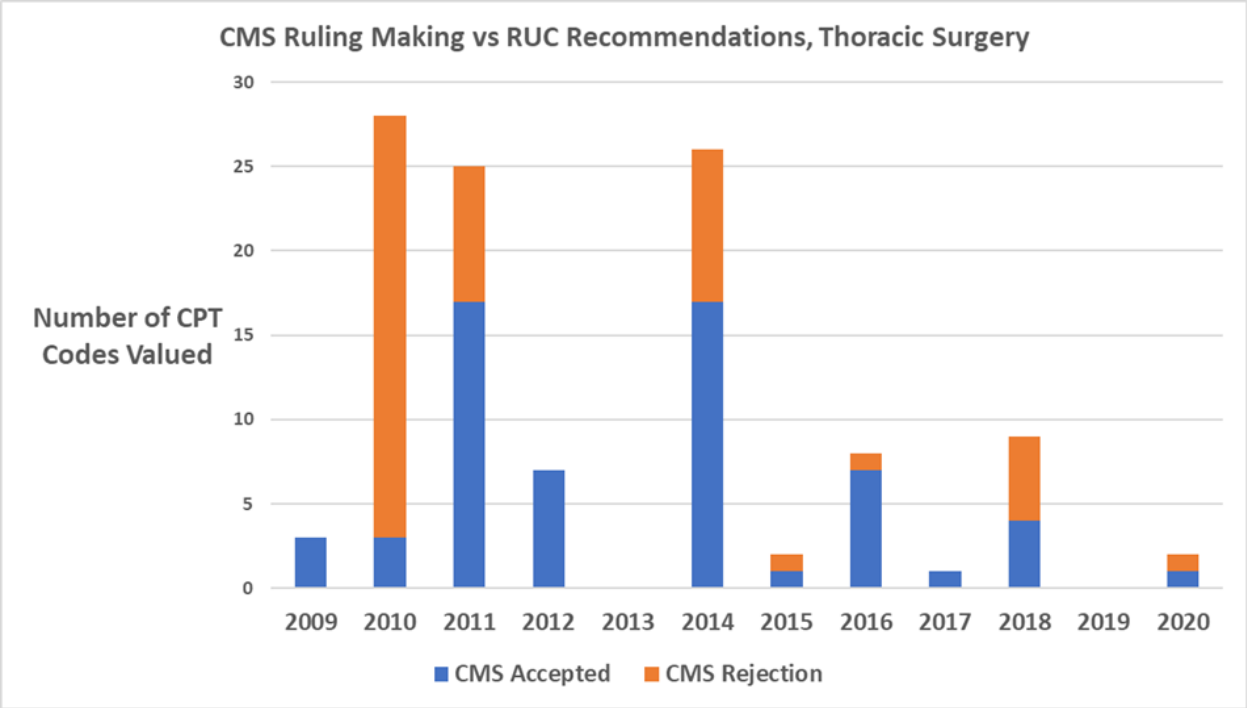
ignoring the intensity of procedures, CMS is also ignoring relativity and at times compelling evidence both of which are critical components in maintaining the Physician Fee Schedule.

When developing recommendations for physician work RVUs, the RUC and specialty societies use objective data (the surveys) and clinical expertise to determine a recommended work value. CMS representatives are present for the discussions and the supporting information, and the clinical rationale and data related to the code recommendations are provided to CMS. However, when CMS rejects the recommended valuations, they rarely, if ever, include any clinical rationale to support their revised (typically decreased) value recommendation. Instead, they continue to use a vast array of possible mathematical calculations to arrive at an arbitrary value, rather than seeking a valid, clinically relevant relationship that preserves relativity. Recommendations for reductions in value by CMS should be made based on a clinical basis, not a random calculation that allows them to achieve the desired decrease in value. At the very least, for some codes, CMS should offer specialties the ability to request a peer-to-peer review with carrier medical directors (CMDs) and/or Medical Officers who are familiar with the services in question. This would not be a refinement panel as CMS has used in the past, but an actual peer-to-peer clinical review of the final value CMS proposes compared clinically with reference codes.

Additionally, all CPT codes that are identified as potentially misvalued should be required to go through the same process as outlined by CMS in Section II.C of this proposed rule. CMS, specialty societies or interested stakeholders should be required to nominate or identify potentially misvalued codes and code families through the prescribed identification and review process instead of proposing to change the RVW for a code by crosswalk based on CMS' or a specialty's perceived rank order anomaly. For example, CMS proposes to adjust the value for one code using a specialty suggested crosswalk after CMS increased other End-Stage Renal Disease (ESRD) codes for CY 2021 that they believed included specific office visits. None of the ESRD codes were identified as potentially misvalued or reviewed through the RUC process. Rather, CMS revalued the ESRD and other services they considered as analogous to office and outpatient E/M visits for CY 2021 without any formal review of the codes. CMS should obtain data to support any changes in the work or practice expense related to any service. All potentially misvalued services should be submitted using the prescribed process and subject to surveys and review by the RUC and to determine if any changes in value are warranted.

STS would like to call CMS' attention to our concerns with the disparate impact to STS and the cardiothoracic surgeons we represent that has resulted from CMS' actions related to the valuation of procedures where STS is the primary specialty. STS reviewed the number of procedures where CMS rejected the RUC recommend values when surveyed by STS as the primary specialty vs all other specialties from 2009 - 2019. Our findings, represented in the graph and table below, indicate that CMS has taken a prejudicial approach to our specialty, regardless of any other evidence to the contrary. In fact, as outlined in our concerns stated above, there is a large amount of corroborating evidence as each individual rejection is not supported by anything approaching an objective evaluation of the RUC recommendations. This trend continues with this proposed rule for CY 2022 where CMS rejected the RUC recommended value for approximately half of the code families where STS was the primary specialty involved (exclusion of left atrial appendage 33XX3, 33XX4, 33XX5 and upper extremity artery harvest 35600 and 35XX0). While CMS accepted the RUC recommend values for the left atrial appendage exclusion codes, they recommended lower values for the upper extremity artery harvest codes using flawed logic based solely on time, without any consideration of intensity and no clinical

rationale to support their proposal. Further, CMS based their whole time decrease argument on a new code instead of using the established code where there was no decrease in time.



RUC Meeting Years	Specialty	Codes Valued by RUC	RUC Value Rejected by CMS	% Rejected
2009-2019	STS	109	49	45%
2009-2019	All Other Specialties	1958	342	17%

9. Harvest of Upper Extremity Artery (CPT 35XX0 and 35600)

In May 2020, the CPT Editorial Panel created a new CPT code 35XX0 (Harvest of upper extremity artery, 1 segment, for coronary artery bypass procedure, endoscopic) to describe endoscopic radial artery harvest via an endoscopic approach and CPT code 35600 (Harvest of upper extremity artery, 1 segment, for coronary artery bypass procedure, open) was modified to only include an open approach for the upper extremity harvesting procedure. The RUC also stated that CPT codes 35XX0 and 35600 are almost always exclusively performed in conjunction with coronary artery bypass grafting (CABG) procedures (33533 -33536). For CY 2022, the RUC-recommended a work RVU of 3.75 for CPT code 35XX0 and a work RVU of 4.00 for CPT code 35600. CMS disagreed with the RUC recommended values for these codes indicating that the RUC-recommended value of 3.75 is higher than other codes with similar intra-service time (35 mins) and total times (35 mins) and are proposing 3.34 as the work RVU for 35XX0. The CMS proposed value is based on a direct crosswalk to code 35686 (Creation of distal arteriovenous fistula during lower extremity bypass surgery (nonhemodialysis) (List separately in addition to code for primary procedure)) and use code 74713 (Magnetic resonance (e.g., proton) imaging, fetal, including placental and maternal pelvic imaging when performed; each additional

gestation (List separately in addition to code for primary procedure)) which has a work RVU of 1.85 as a reference code to support their argument. CMS is proposing a work RVU of 3.59 for 35600. CMS agreed with the RUC-recommended interval of 0.25 RVUS as the relative difference in work between CPT codes 35XX0 and 35600 and based their proposed work value of 3.59 on a 0.25 RVU increase above the CMS recommended RVU of 3.34 for code 35XX0. There are no direct PE inputs for these codes since the services are provided exclusively in the facility setting.
CMS is also proposing to assign these two codes a ZZZ-day global period despite the RUC recommendation to assign an XXX-day global period. CMS indicates that since ZZZ-day global period codes were used to survey the two upper extremity artery harvest codes and their scrutiny of comparing code descriptors of codes with matching intraservice times, they find that the ZZZ-day global period is more clinically coherent than codes with an XXX-day global period and as such, they believe that it is appropriate to assign ZZZ-day global period for codes 35XX0 and 35600 and are proposing that a ZZZ-day global period be assigned to the both codes for CY 2022. However, CMS has indicated that they are seeking comments to inform them why CPT codes 35XX0 and 35600 should have an XXX-day global period instead of the ZZZ-day global period that is customary for add-on codes.

<u>35XX0 and 5600 Global Period Assignment</u>
The rationale for assigning these services an XXX-day global period instead of a ZZZ-global period, even though the service is almost exclusively performed in conjunction with an arterial CABG procedure (CPT codes 33533 – 33536) is that an XXX-day global period would allow the individual who performs the harvest of upper extremity artery procedure (often separate from the surgeon performing the base CABG procedure and not the first assistant) to report it under their NPI number. In response to this, CMS proposed to reject this request for an XXX-day global period assignment and designate both services as add-on codes with a ZZZ-day global period.

Although CMS proposed to assign these services a ZZZ-day global period, the Agency also noted that they are compelled to understand more about the billing circumstances cited by the RUC. Beyond what is stated above, the societies involved in surveying the codes (STS, AAPA and ANA) had also indicated that sometimes the separate physician or other qualified healthcare professional QHP (typically a PA or NP) performing the harvest procedure is not part of the same practice as the surgeon performing the CABG procedure or is not the first assistant for the CABG surgery. Since a separate provider performing the harvest procedure is not part of the same practice, there would be no established mechanism for paying this provider for their work. Similarly, if the physician or QHP who performs the upper extremity artery harvest is in the same practice but is not the first assistant at the CABG surgery, they have no mechanism to report an add-on code since they are not reporting an arterial CABG code. In both situations, the individual performing the upper extremity artery harvest procedure does not have a primary code with which to report the add-on code which would result in the codes being denied for payment. Even if the individual performing the upper extremity artery harvest is also the first assistant at surgery and reports an arterial CABG procedure with an appropriate assistant at surgery modifier (-80, -82 or -AS), the add-on code, which is only reported by the assistant at surgery, is not recognized by payers. By assigning an XXX-day global period to these codes and valuing them as ZZZ-day global codes, the individual that performs the upper extremity artery harvest service can report the procedure without also having to report an arterial CABG code, thereby ensuring that the provider

that performed the radial artery harvest procedure is reimbursed at the appropriate rate (e.g., physician vs NP or PA).

As to why the two codes (35XX0 and 35600) proposed as XXX codes were, nevertheless, surveyed using a reference service list with ZZZ-day global codes was to ensure that the codes were valued in the same manner as an add-on code with no pre or post service work included in the procedure. STS recognizes that, as CMS points out, these codes are worded in the same manner as most add-on codes and only include the additional work of harvesting the upper extremity artery. While STS agrees that these codes are, in essence, add-on procedures, they are unique in that the additional intra-operative work represented by the procedures is typically performed by individuals that specialize in harvesting the grafts for CABG procedures. These individuals may or may not be associated with the same practice as the surgeon performing the procedure and may not perform another service related to that case. In addition, when referencing that the harvest procedure is almost always performed with a CABG procedure, CMS noted that *"…such codes are designated as add-on procedures and are assigned a ZZZ-day global period (that is, code related to another service and is always included in the global period of the other service)."* However, that is not the case for services that are performed by a separate provider other than the surgeon performing the primary procedure. A relatively recent example of services like this are the separate provider moderate sedation codes 99155-99157 which CMS assigned an XXX global period.

STS also has significant concerns with CMS' and to some degree, the discussion that occurred during the RUC proceedings, that these codes should be devalued at the RVU level since they are often performed by PAs or NPs. The work associated with a specific code is supposed to be valued based on work of the procedure regardless of who provides the service. The payment amount is adjusted though the MPFS payment rule that reimburses NPs and PAs at 85 percent of the Medicare physician fee schedule (MPFS) rate. The performing provider should not factor into the RUC and CMS valuation discussions when determining the appropriate work values for a procedure.

STS urges CMS to accept the specialty and RUC recommended XXX global period assignment for codes 35XX0 and 35600.

35XX0

For CPT Code 35XX0, CMS disagrees with the RUC recommended work RVU of 3.75 and proposes a work RVU of 3.34, based on a direct work RVU crosswalk to CPT code 35686 Creation of distal arteriovenous fistula during lower extremity bypass surgery (non-hemodialysis) (List separately in addition to code for primary procedure) (work RVU=3.34, intra-service and total time of 35 minutes).

CMS supported this recommendation by referencing CPT code 74713 *Magnetic resonance (eg, proton) imaging, fetal, including placental and maternal pelvic imaging when performed; each additional gestation (List separately in addition to code for primary procedure)* (work RVU= 1.85, intra-service time and total time of 35 minutes). However, unlike both of these reference codes, the survey code is typically performed by a separate provider than the one that is performing the base procedure. STS is concerned that CMS did not take into consideration the intraoperative evaluation and intensity associated with the procedure, which also contributed to

the RUC's recommendation for a value that is higher than other procedures with similar intra and total times. Also, the reference code CMS used as a direct work RVU crosswalk has not been reviewed by the RUC or CMS in 20 years and has virtually no volume. Furthermore, the reference code 74713 that CMS cited as support for their proposal, is an imaging code that has no clinical similarities to the survey code. There are a number of codes reviewed by the RUC between 2011 and 2016 with 30 mins of intra time and 30 mins of total time (less than that of both surveyed codes) with wRVUS of 3.50 – 4.33 (37247, 32674, 38746, 36909, 36228, 61641), many of which represent procedures more closely related to cardiothoracic surgery than code 74713 and more recently valued than 35686.

If CMS were to consider code 35600 first, recognizing that the recommended value of 4.00 (a 19% decrease from the current value for the same amount of intra and total time) is well supported by the RUC survey and a number of refence codes, and base their logic to apply the 0.25% interval difference, which was derived from the RUC surveys, to code 35XX0, the RUC recommended value of 3.75 for 35XX0 would be seen to be reasonably supported by the RUC surveys and the indicated reference codes.

STS urges CMS to accept the RUC recommended work RVU of 3.75 for CPT code 35XX0.

35600

For CPT code 35600, CMS disagrees with the RUC recommended work RVU of 4.00 and proposals a work RVU of 3.59, based on the increment between the RUC recommended values between 35XX0 and 35600 of 0.25. CMS indicated that the reason for their rejection of the RUC recommended value was based on a review of services with similar intra-service and total times, though did not list any specific reference codes for this service.

If CMS had reviewed reference codes for 35600, they would find ample support for the RUC recommended value of 4.00. Code 34812 is a recently valued (2017) code that is also performed by cardiothoracic surgeons. As pointed out by the RUC, this code is similar in work, has 40 mins of intra time and 40 mins of total time with a RVU of 4.13 and an IWPUT of 0.1032. Codes 36908 (valued in 2016) and 93462 (valued in 2010) also have 40 mins of intra and total time with wRVUs of 4.25 and 3.73 and IWPUTs of 0.1062 and 0.0932 respectively. Codes 36908 and 93462 represent transcatheter procedures and 34812 and 35600 both represent procedures performed through open incisions. As previously mentioned, there are also a number of codes that were reviewed by the RUC between 2011 and 2016 with 30 mins of intra time and 30 mins of total time (less than that of both surveyed codes) with wRVUS of 3.50 – 4.33 and intensities ranging from 0.1167 – 0.1443 (37247, 32674, 38746, 36909, 36228, 61641). All of these codes support the time and intensity associated with cardiovascular and thoracic procedures that represent additional intraoperative work. The RUC recommended value of 4.00, the 25th percentile from the RUC survey, with an intensity of 0.100 represents a well-supported and appropriate work value for code 35600 which has an intra time and total time of 40 minutes, 10 minutes more than the codes listed with a slightly lower IWPUT. The CMS recommended value of 3.59 lowers the intensity to 0.090, well below that of the other surgical add-on procedures. The wRVU of code 35600 is decreasing by 19% **even though the surveys supported the same intra and total time as the current code** which has a higher valuation of 4.94. If CMS would have considered the work associated with code 35600 with a RUC recommended value of 4.00 with

40 mins of intra time and 40 mins of total time (a 19% decrease in value for the code which is currently valued at 4.94 with 40 mins of intra time and 40 mins of total time) and then applied the 0.25% interval difference, which was derived from the RUC surveys at the 25 percentile, to code 35XX0, the RUC recommended value of 3.75 for 35XX0 is reasonably supported, both by CMS' logic, reference codes and the RUC surveys.

STS urges CMS to accept the RUC recommended work RVU of 4.00 for CPT code 35600.

12. Per-Oral Endoscopic Myotomy (POEM) (CPT codes 434XX)

In May 2020, the CPT Editorial Panel created a new CPT code 434XX (Lower esophageal myotomy, transoral (i.e., peroral endoscopic myotomy [POEM])) to describe a Per-Oral Endoscopic Myotomy (POEM), which involves the visualization and dissection of the esophageal muscle layers via an endoscope to treat esophageal motility disorders such as achalasia. This procedure accomplishes a comparable myotomy to what traditional open and laparoscopic myotomy (Heller) accomplishes. POEM utilizes an endoscope and specially designed dissecting, cutting, and cauterizing instruments to create a long submucosal tunnel beginning in the mid-esophagus and extending several centimeters into the cardia. For CY 2022, the RUC recommended a work RVU of 15.50 for CPT code 434XX. CMS disagrees with the RUC-recommended work RVU for CPT code 434XX and is proposing a work RVU of 13.29 based on a direct work RVU crosswalk from CPT code 36819 (Arteriovenous anastomosis, open; by upper arm basilic vein transposition which has the same 120 minutes of intra service time as CPT code 434XX, and has 283 minutes of total time, which is 2 minutes more than the 281 minutes of total time than for 434XX. The RUC used CPT codes 43279 (Laparoscopy, surgical, esophagomyotomy (Heller type), with fundoplasty, when performed) and 43180 (Esophagoscopy, rigid, transoral with diverticulectomy of hypopharynx or cervical esophagus (e.g., Zenker's diverticulum), with cricopharyngeal myotomy, includes use of telescope or operating microscope and repair, when performed) as reference codes for CPT code 434XX. However, the intra service time of 150 minutes and total time of 404 minutes for the RUC reference CPT code 43279, and intra service time of 60 minutes and total time of 201 minutes for the RUC reference CPT code 43180, are not adequate comparisons since they do not have similar time values to those of CPT code 434XX. CMS proposed a work RVU of 13.29 for CPT code 434XX based on a direct work RVU crosswalk from CPT code 36819 which they consider is a better representation of the work being performed and is more appropriate based on the same intra service time and similar total time.

Of note, the RUC database states 36819 should not be used for comparison as CMS did not accept the specialty society or RUC recommended values. Interestingly the RUC recommended value for 36819 was 15.00 much closer to the 15.50 RUC recommendation for 434XX

Code 434XX is a new code where the RUC recommended value was supported by a robust survey. There is no decrease in time or statement of intensity for new codes as with codes undergoing revaluation. As with most recommendations from CMS, they provided rationale as to why they dismissed the survey data from 119 gastroenterologists, gastrointestinal surgeons and thoracic surgeons and expert panel for this code in favor or a direct crosswalk where they also ignored survey data and expert opinion. In their rationale, CMS again disregarded intensity associated with the procedure and referenced time alone as their reason to use a direct CPT

crosswalk in their recommendation for a lower work RVU for code 434XX which creates a rank order anomaly disrupting relativity in the fee schedule.

The intensity and complexity associated with POEM is reflected in several aspects of the procedure. POEM is an axial procedure performed with a single tool with a limited field of view looking down the same axis as the tool. The procedure is performed using a flexible endoscope which is harder to maneuver than the more rigid laparoscope. The limited view and diminished maneuverability associated with the procedure may increase the severity associated with adverse events that may occur during the procedure in that a significant bleed or perforation could require emergency surgery.

CMS proposes to use a direct crosswalk based on time for their proposed work RVU. CMS explains that it rejected the codes the RUC used to support the survey data (43279 and 43180) because they do not have identical times to POEM. However, the codes provided by the RUC were never meant to be crosswalk codes; they are reference codes that act as bookends to demonstrate how the value of 434XX falls appropriately between them thereby maintaining relativity. They are also the top two key reference services (KRS) selected by the survey takers: 43279, *Laparoscopy, surgical, esophagomyotomy (Heller type), with fundoplasty, when performed*, (work RVU = 22.10; 150 minutes intra-service time) and 43180, *Esophagoscopy, rigid, transoral with diverticulectomy of hypopharynx or cervical esophagus (eg, Zenker's diverticulum), with cricopharyngeal myotomy, includes use of telescope or operating microscope and repair, when performed*, (work RVU = 9.03; 60 minutes intra-service time). It is logical that the survey takers migrated towards the top two KRS codes based on their familiarity with these procedures and the disease states treated by these procedures. As is typical with the RUC process, reference codes are intended to act as supporting rationale to demonstrate relativity within the fee schedule. 43279 and 43180 are representative of this concept in that they demonstrate the validity of the 15.50 RVU recommendation for 434XX, which falls between the established RVUs of 43279, the longer more intense procedure, and 43180, the shorter less intense procedure. The RUC also provided Multi-specialty Points of Comparison (MPC) codes 19303, *Mastectomy, simple, complete,* (work RVU = 15.00; 90-minutes intra-service time) and 60500, *Parathyroidectomy or exploration of parathyroid(s)*, (work RVU = 15.60; 120 minutes intra-service time) to further support its recommendation of 15.50 wRVUs.

The surveying specialty societies provided the RUC with tables that contained additional comparison codes with similar time, intensity and post-operative visits which demonstrated the appropriateness of the 15.50 RVU for 434XX. Reference codes included in the tables represented surgical procedures from several different specialties and showed relativity within the fee schedule. The codes that were included in the tables were 58674, 58543, 19303, 57265, 58571, 58544, 60500, 15733, 43279. All of them are 90-day global procedures valued between 2010 and 2017, and one code valued in 2008. The post-operative visits for most codes were similar, most with a 0.5 discharge day and 2 99213 office visits. Work RVUs for the codes ranged from 14.08 – 22.10 with intra-service times between 90 and 150 minutes, total times ranging from 241 – 404 minutes and IWPUTs of 0.0825 and 0.119. At the RUC recommended RVW of 15.50 with 120 minutes of intra time and 261 minutes of total time, code 434XX fell in the middle of the range of codes with an IWPUT of 0.095. The code range provided included two MPC codes (19303 and 60500).

As previously pointed out, CMS' recommendation to crosswalk code 434XX to 36819 is based only on time and fails to take into consideration the difference in intensity between the procedures. Code 36819 represents one of many codes that CMS could have selected to use as a crosswalk based on time. Value is based on multiple factors including procedure time, technical skill required, physical effort involved, mental effort and judgment, and stress due to the potential risks to the patient. If CMS were to truly have considered intensity in addition to time, the selected crosswalk should have reflected this consideration by selecting a code with similar intensity. A search of the RUC database for 90-day global codes with 120 minutes of intra-service time yields 235 CPT codes with IWPUTs ranging from -0.036 to 0.1983.

CMS' recommended work RVU of 13.29 for code 434XX creates a rank-order anomaly in the intensities of related procedures. The RUC noted in its recommendation to CMS that CPT code 43180 requires much less physician time, work and intensity than CPT code 434XX. Additionally, 74% of the survey respondents who selected key reference code 43180 indicated overall, 434XX was more intense and complex to perform than 43180. However, the IWPUT of 43180 is 0.0855, which is *higher* than the 0.073 IWPUT resulting from CMS' recommended RVU of 13.29 for 434XX.

STS urges CMS to accept the RUC recommended value of 15.50 for code 434XX.

F. Evaluation and Management Visits

1. Split/Shared Services

CMS defines a split (or shared) visit as an evaluation and management (E/M) visit that is performed ("split" or "shared") by both a physician and an NPP who are in the same group. While E/Ms performed in the office have the option to be billed under the "incident to" rules when a portion of the service is furnished by an NPP, those policies do not apply to E/Ms performed in facility settings.

STS supports CMS' efforts to clearly define split/shared E/M visits in the facility setting when performed in part by both a physician and an NPP who are in the same group in accordance with applicable laws and regulations. We agree with CMS that the practice of a team-based approach to care has evolved over time allowing for greater integration in the practice of physicians and NPPs, particularly when care is furnished by practitioners in the same group in a facility setting. We support the proposal to permit the physician or NPP to bill for split/shared visits for both new and established patients, as well as for initial and subsequent visits, critical care and nursing facility services.

CMS also proposes to require that the split/shared visit should be billed by the physician or NPP who performs the substantive portion of the visit. They propose to define "substantive portion" as more than half of the total time spent by the physician or non-physician practitioner performing the visit. CMS acknowledges that the billing practitioner who provided the substantive portion of the visit, could use time or medical decision making (MDM) to select the level for the split/shared E/M visit. However, they propose to base the definition of substantive portion on the amount of time spent by the physician and NPP providing the visit, requiring the practitioners to track and document the time they spent for these visits. STS is concerned that this approach is confusing and adds unnecessary complexity to the process. By mandating the practitioners to track and document time for split/shared visits, CMS is in essence,

forcing practitioners into picking time as the billing criterion for these visits. To have both practitioners track time, decide which of them is the substantive provider, communicate this determination with each other and then have the billing provider decide between billing the split/shared visit on total time or MDM is not practical for most practitioners and creates a significant administrative burden. To require practitioners to document and track their time over the course of the day and be aware of the other practitioner's time spent with the patient over the course of the day is unrealistic. While we understand CMS' need to ensure that both practitioners are providing appropriate services to the patient, we believe that there are more practical and less burdensome methods in which to achieve this goal. Additionally, not all time spent is equivalent in terms of provider work. If the NP spends greater than 50% of the total time gathering the appropriate history and doing the directed physical exam, CMS is claiming that is more valuable than the time spent by the physician on medical decision making. There is no basis for this assumption. Yet again, CMS is relegating provider reimbursement to purely time and ignoring intensity.

The previous guidelines defined a split/shared E/M visit as *"a medically necessary encounter with a patient where the physician and a qualified NPP each personally perform a substantive portion of an E/M visit face-to-face with the same patient on the same date of service"* A substantive portion of an E/M visit involved all or some portion of the history, exam or medical decision-making key components of an E/M service. Under the new guidance, the billing practitioner should be able to select the level for the split/shared visit based on medical decision making (MDM) or substantive time. Documentation requirements should require each practitioner to document the services they provide to the patient, which may include a medically necessary history and physical exam, the MDM components they provided and/or time and referencing the other practitioners notes as appropriate. This documentation alone should be sufficient to support billing the code under the MD's name and payment made at 100% of the Medicare Physician Fee Schedule, not the 85% NPP reimbursement rate. This would be similar to the requirements in previous years where the physician was required to perform a face-to-face encounter, personally evaluate the patient, and document their own evaluation (History, Exam and/or MDM) referencing the NPP note for any billing components not included in the documentation.

STS does, however, support the CMS proposal to extend the spilt/shared visits to include prolonged services. We also agree that, in order to avoid potential payment issues, only one practitioner bills the E/M visit and the prolonged service code. The documentation requirements for split/shared prolonged service visits should be similar to those we outlined above.

STS agrees with CMS' list of qualifying activities, which are based on the CPT manual E/M guidelines, that could count toward total time when performed and regardless of whether or not they involve direct patient contact for split/shared visits. CMS requested feedback on whether there should be a different listing of qualifying activities for purposes of determining the total time and substantive portion of split/shared emergency department visits, since those visits also have a unique construct. In order to streamline guidelines and simplify the requirements for split/shared visits, STS recommends that CMS adopt the list of qualifying activities for any given code set (inpatient, ED, critical care) from the CPT manual. Therefore, the qualifying criteria would only be different if there is a difference in guidance for code sets in the CPT manual, but the requirements for any given type of E/M service (inpatient/ ED/ critical care) would be consistent between CPT and CMS.

CMS proposes requiring a modifier be appended to shared/split visits to provide them with insight on when shared/split visits are billed and identify which practitioner is billing the service through claims data instead of only through medical record review. STS discourages CMS from creating a new modifier for split/shared visits. Creation of a new modifier for shared/split visits adds complexity to the process in addition to creating extra administrative burden for the physician, NPP and the coding staff who will have to review many notes to ensure modifiers are attached appropriately. The majority of EMRs are set up to document all providers rendering patient care on the same date of service and split/shared visits would be supported by documentation in the medical record upon medical review. STS does not support CMS' proposal to implement a new modifier to identify split/shared visits. However, if CMS decides to move forward with creation of a new modifier for these services, we encourage them to delay implementation until at least CY 2023 to allow adequate time for education and implementation in medical practices.

CMS proposes that the physician and NPP must be in the same group in order for them to bill for a split/shared visit. CMS seeks comments on whether it should further define "group" for split/shared visit billing purposes. They do not propose a definition in this proposed rule but have considered several options which include the following:

- Requiring that the physician and NPP are in the same clinical specialty
- Aligning the definition of "group" with the definition of "physician organization" in the self-referral law
- Defining the group as practitioners "billing under the same billing tax identification number". CMS has expresses concerns that some groups are too large to assume that all the practitioners work closely enough to allow split/shared billing.

STS recommends that CMS not further define "group" for the purposes of split/shared visits at this time. Practitioners have the ability to determine if the care they provide to patients qualifies as a split/shared visit. However, if CMS decides to further define the term "group" for the purpose of billing split/shared visits, we suggest that they use the definition requiring that the physician and NPP be in the same clinical specialty. This definition would align with CPT guidelines in which the NPP is considered to be in the same specialty and subspecialty as the physician with whom they are working.

2. Critical Care Services

CMS includes a series of proposals in the rule to update its critical care E/M policy to improve transparency and clarity and account for recent revisions to the E/M visit coding and payment. CMS proposes that critical care services may be reported by an NPP that meets the definition of a qualified healthcare professional (QHP) and to allow for split/shared billing of the initial critical care services code. CMS also provides clarification that critical care services may be furnished as concurrent care to the same patient on the same day by more than one practitioner in more than one specialty… regardless of group affiliation, if the service meets the definition of critical care and is not duplicative of other services. However, if the providers are from the same specialty and in the same group and furnish care on the same day, one provider reports 99291 and the second provider must use CPT 99292 so that 99291 is not reported more than once per day. CMS also states that a provider may not bill other E/Ms on the same day a critical care service is billed. Finally, CMS notes that critical care visits are already included in some 10- and 90-day global surgery codes. Because of that and their continued work to assess global surgery values, CMS proposes to bundle critical care visits with procedure codes that have a global surgical period. This would replace their current policy that allows unrelated critical care visits to be reported on

the same day as a procedure code with 10- and 90-day global periods. The current policy requires that modifier -24 or -25 be appended to the critical care code to indicate that the critical care service is unrelated to the procedure performed.

For the most part, STS is supportive of CMS updating the critical care E/M visit policies to improve transparency and clarity, and to account for recent revisions to E/M visit coding and payment policies. STS agrees with CMS' proposal to adopt the CPT prefatory language as the definition of critical care services. The CPT prefatory language states that "critical care is the direct delivery by a physician(s) or other qualified healthcare professional (QHP) of medical care for a critically ill/injured patient in which there is acute impairment of one or more vital organ systems, such that there is a probability of imminent or life-threatening deterioration of the patient's condition. Critical care involves high complexity decision-making to treat single or multiple vital organ system failure and/or to prevent further life-threatening deterioration of the patient's condition." STS also supports CMS' adoption of CPT's listing of services that are bundled into critical care and should not be separately reported.

We appreciate CMS' recognition that physicians providing critical care services furnished concurrently by different specialties is not duplicative but complementary. CMS indicates that "concurrent care may be medically necessary because of the existence of more than one medical condition requiring diverse specialized medical services, that is, more than one specialty which can include a qualified NPP as a specialty. In the context of critical care services, a critically ill patient may have more than one medical condition requiring diverse specialized medical services and thus requiring more than one practitioner having different specialties to play an active role in the patient's treatment." We fully support CMS' proposal to cover concurrent critical care services provided to the same patient on the same day by more than one practitioner in more than one specialty when the service of each practitioner meets the definition of critical care, are medically necessary, and not duplicative. CMS indicates that they are seeking information on their proposal related to concurrent critical care "to better understand current clinical practice for critical care, and when it would be appropriate for more than one physician or NPP of the same or different specialties, and within the same or a different group, to provide critical care services."

STS offers the following clinical scenarios supporting payment for concurrent services that meet the definition of critical care by the same or different specialties to the same patient on the same day:

1) Critical care services may be furnished concurrently to the same patient on the same day by a cardiac surgeon and a cardiologist where the cardiac surgeon is following the patient after a CABG procedure and the cardiologist is following the patient for an underlying condition such as atrial fibrillation with a fast ventricular response and hemodynamic compromise or heart failure.
2) A general thoracic surgeon provides critical care services to a patient following an esophagogastrectomy procedure for acute esophageal perforation with sepsis and a general surgeon critical care specialist provides critical care to the same patient for the multi-system organ dysfunction/failure related to the sepsis.
3) A cardiac surgeon, who is a same specialty partner in a group that performs a cardiac procedure and provides critical care services to the patient related to their cardiac surgery and contained in the procedure's global period, also works in the hospital as an intensivist and provides critical care to the same patient unrelated to the cardiac

surgical procedure for example acalculous cholecystitis or toxic megacolon secondary to c. difficile colitis.

CMS proposes to maintain their current policy which indicates that, for critical care furnished concurrently by two or more practitioners in the same specialty and in the same group to the same patient on the same day, the individual physician(s) or NPP providing the follow-up or subsequent care report their time using the code for subsequent time intervals (CPT code 99292) and would not report the primary service code (CPT code 99291). CPT code 99291 would not be reported more than once for the same patient on the same day by these practitioners. CMS proposes to deviate from CPT coding guidance where CPT conventions indicate that a practitioner who furnishes a timed service such as critical care would typically need to report the primary service or procedure code before reporting an add-on code. This would result in the total time for critical care services that are furnished to a patient on the same day by the practitioners in the same group with the same specialty being reported using 99291 for the initial critical care time and 99292 for all additional critical care provided to the patient on the same day.

In reviewing and updating their guidance to better reflect current medical practice, CMS proposes to allow critical care service time spent by more than one practitioner in the same group with the same specialty to be added together for the purposes of meeting the time requirement to bill for the initial critical care service using CPT code 99291 and then each additional time increment that meets the CPT definition and criteria and is medically necessary is reported with code 99292. STS supports CMS' proposal that critical care services provided to the same patient on the same day by same specialty physicians and/or NPPs in the same group can be aggerated over the day to meet the time criteria to report code 99291. Once that time criteria is met, code 99292 should be reported for any additional aggregate critical care in increments of 30 minutes provided to the patient for that day.

STS also supports the CMS proposal to allow critical care services to be reported when furnished as a split/shared service. The split/shared visit criteria would be the same as those outlined for the split/shared visits in Section II (F)(1) of this rule requiring the practitioner who furnishes the substantive portion of the cumulative critical care time to report the critical care service(s). However as stated above in the split/shared visit comments, STS does not support requiring the proposed new modifier on the claim.

Another CMS proposal specifies that no other E/M visit (e.g., ED, inpatient or office/outpatient) can be billed for the same patient on the same date as a critical care service when the services are furnished by the same practitioner, or by practitioners in the same group/specialty. STS disagrees with this proposal. We believe that practitioners should be able to bill for all medically necessary services that are furnished to a patient. Clinical presentations vary from patient to patient, and it is not unreasonable that a patient my present to same specialty practitioners for medically necessary reasons more than once in a day, in which case both visits should be separately billable. For example, a cardiac surgeon might see a patient for a routine monitoring checkup for an aortic aneurysm and then later that day, the patient may present to the emergency room with an acute MI where the same cardiac surgeon or one of their same specialty partners provides critical care services. Both visits are medically necessary. As such, the physician(s) should be allowed *to bill for their evaluation and management services as well as the critical care performed later that day by the same physician or same specialty members of the group.* CMS by proposing that no other E/M visit can be billed for the same patient on the same date as a critical care

service when the services are furnished by the same practitioner, or by practitioners in the same group/specialty totally ignores the purpose of modifiers -24 or -25 which can be appended to the critical care code indicating that the critical care service is unrelated to the procedure performed. CMS in this proposal is not compensating providers for medically necessary work.

CMS also proposes to bundle critical care visits with procedure codes that have a global surgical period. CMS bases this proposal on the premise that critical care visits are included in some 10- and 90-day global packages and that, because they are still in the process of assessing the values for global surgery procedures, including in particular the number and level of preoperative and postoperative visits, which can include critical care services, the critical care services should not be separately billable regardless of the circumstances. This proposal directly contrasts with CMS' current policy which allows critical care visits to be reported in addition to a procedure with global surgical period as long as the critical care service is unrelated to the procedure, which requires appending modifier -24 (or -25) to the critical care service to pull it out of the global surgical package with supporting documentation.

STS strongly disagrees with CMS' proposal not to allow practitioners to bill for unrelated critical care services during the global period of a procedure. It is not uncommon that unrelated critical care services may be needed on the same calendar date as a procedure code with a global surgical period. CMS provides no reason other than that of their on-going assessment of the global surgical package to support their proposal to always bundle critical care with procedures that have 10- and 90-day global periods. It is unreasonable and would be clinically irresponsible, putting patient care at risk if CMS were to implement this proposal. Critical care services provided by a physician, NPP or one of their same specialty partners in the group that are unrelated to the surgery should be separately billable. Use of the -24 and -25 modifiers for critical care services rendered that are not considered part of the global surgical package of a procedure with supporting documentation included in the medical record should be adequate to ensure that any critical care services billed during the global surgical period of a procedure are unrelated. Critical care services that are valued into the global surgical package are specifically related to the procedure performed and would not in any way overlap with critical care provided for unrelated reasons. Unrelated critical care would require different work, time, complexity and effort related to treating the patient's new, unrelated disease process and the additional work of the physician or NPP should be reimbursed appropriately.

STS urges CMS to maintain their current policy to allow unrelated critical care to be billed in addition to procedures with a global surgical package provided the critical care services are medically necessary, the appropriate modifier (-24 or -25) is appended to the critical care code and there is documentation in the patient's medical record supporting this criterion. CMS can watch for providers that abuse this guidance by monitoring the frequency with which critical care services are reported during the global period of a procedure with and/or without the -24 or -25 modifiers.

G. Billing for Physician Assistant (PA) Services

CMS proposes to implement provisions included at Section 403 of the Consolidated Appropriations Act, 2021, that authorized PAs to bill the Medicare program and be paid directly for their services in the same way that Nurse Practitioners (NPs) and Certified Nurse Specialists (CNSs) do.

STS supports CMS' proposal to amend and update relevant sections of their regulations effective, January 1, 2022, authorizing PAs to bill the Medicare program and be paid directly for their services in

the same way that NPs and CNSs are paid. Including the PAs ability to reassign their rights to payment for their services, incorporate as a group comprised solely of practitioners in their specialty and bill the Medicare program will ensure that payment is made to a PA for professional services furnished by a PA in all settings in both rural and non-rural areas. We agree that payment should only be made to the PA provided that no facility or other provider charges are paid beyond reimbursement for services furnished by the PA. We appreciate that CMS notes that this does not affect the physician supervision requirements for services delivered by PAs.

IV. Quality Payment Program (taken out of order)

d. Closing the Health Equity Gap in CMS Clinician Quality Programs—Request for Information
CMS discusses its commitment to health equity and seeks feedback on improving data collection to allow for better measurement and reporting on equity across its programs and policies.

STS commends CMS for its attention and efforts to close the health equity gap in QPP. STS recognizes disparities in access to health care and health outcomes and is deeply committed to the elimination of racial bias and disparities in health care. We are striving to achieve equity in health care across race/ethnicity, age, gender identify, sexual orientation, nationality, socioeconomic status, and geographic background. These inequities exist across health care and cardiothoracic surgery is no exception. Improving health equity in cardiothoracic surgery is a top STS advocacy priority and remains a focus of STS quality initiatives.

The STS Workforce on Health Policy, Reform, and Advocacy identified improving health equity as a top 2021 STS advocacy priority. STS advocacy efforts support research on disparities, legislation that advances equity in access, educating policymakers on how the STS National Database can be used to inform health outcomes, and encouraging diversity, equity, and inclusion in the health care system. The STS Workforce appointed a workgroup to develop a position paper that will guide advocacy efforts to improve health equity in cardiothoracic surgery. STS also recognizes the importance of race and gender representation in the cardiothoracic workforce in improving access and outcomes for patients. The STS Workforce on Diversity and Inclusion recently published an approach for addressing diversity and inclusion in cardiothoracic surgery, adapted from a model developed by the National Institute on Minority Health and Health Disparities.[2] The multilevel framework (global environment, cardiothoracic community, institution, and individual) offers an organized approach for cardiothoracic surgery to assess, improve, and sustain progress in diversity and inclusion.

The STS Research Center is also engaged in efforts to improve the STS Database understanding of socioeconomic indicator impact on inequitable patient outcomes. STS recently developed the ability to incorporate block level Area Deprivation Index (ADI)[3] data, which gives more specific insight into block level domains of income, education, employment, and housing quality. By engaging in this research, STS hopes to gain insight into how societal factors can impact patient outcomes.

STS supports the CMS effort to identify and improve health equity gaps in the Medicare QPP and has provided feedback to specific CMS request for comment below:

[2] Erkmen CP, Ortmeyer KA, Pelletier GJ, Preventza O, Cooke DT; Society of Thoracic Surgeons Workforce on Diversity and Inclusion. An Approach to Diversity and Inclusion in Cardiothoracic Surgery. *Ann Thorac Surg.* 2021;111(3):747-752. doi:10.1016/j.athoracsur.2020.10.056
[3] https://www.neighborhoodatlas.medicine.wisc.edu/

Improving demographic data collection: CMS seeks current data collection practices by hospitals to capture demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), language preference, tribal membership, and disability status). CMS also is interested in potential challenges with collecting a minimum set of demographic data elements in alignment with national data collection standards (such as the standards finalized by the Affordable Care Act) and standards for interoperable exchange (such as the USCDI). Finally, CMS seeks comments on other efforts it can take within the MIPS program to further bridge the equity gap.

STS supports implementing standards for hospitals to improve demographic data collection.

Separate from the RFI, CMS also discusses other proposals in this rule related to further bridging the health equity gap within the MIPS track of QPP:

-Improvement Activities: CMS discusses a proposed improvement activity titled "create and implement an anti-racism plan" that acknowledges it is insufficient to gather and analyze data by race, and document disparities by different population groups. Instead, it emphasizes a systemic racism is the root cause for differences in health outcomes between socially defined racial groups. CMS also proposes to modify five existing improvement activities to address health equity.

STS supports improvement activities aimed at addressing health equity. We encourage facility administrative staff and clinicians to work together in identifying the appropriate resources, infrastructure, and educational opportunities to create and implement anti-racism plans. We encourage inclusion of such plans in hospital incentive programs so that hospitals may attest to having and implementing an organizational plan and the individual clinician or group may report participation in the plan.

-Complex Patient Bonus Formula: CMS proposes to update the complex patient bonus formula to make the complex patient bonus more targeted for clinicians caring for high risk and complex patients and to mitigate differences in resources that affect MIPS scores.

STS supports updating the complex patient bonus to better target clinicians who treat a higher caseload of more complex and high-risk patients in the MIPS and MVP programs. This bonus plays a role in improved patient access by helping alleviate risk aversion. STS identifies two items for further CMS consideration. First, using the Hierarchical Condition Categories (HCC) on CMS administrative claims data alone is insufficient. STS strongly recommends that CMS use clinical data, which is more reliable for determining comorbidities, alongside administrative claims data. Second, we encourage CMS not to limit social risk determination solely to dual-eligibility. There are many other indicators of social risk necessary to capture the full scope of patients who might have risk factors that contribute to the complexity of care they need. Although identifying the full scope of patients with social risk is a complex task, STS encourages CMS to continue to work with stakeholders to design a more inclusive, reliable, and accurate method to account for complex patients.

-Promoting Interoperability Weight Redistribution: To further alleviate the burden on small practices and reduce this disparity between large and small practices, CMS proposes to automatically redistribute the Promoting Interoperability performance category weight for any small practice that does not submit data for the performance category and different redistribution weights for small practices.

STS supports this CMS proposal.

3. MIPS Program Details
b. Transforming MIPS: MIPS Value Pathways (MVPs)

CMS proposes seven MVPs on the following topics: Rheumatology, Stroke Care, Ischemic Heart Disease, Chronic Disease Management, Emergency Medicine, Lower Extremity Joint Repair, and Anesthesia. CMS anticipates that the portfolio of MVPs would continue to grow over the next few years. CMS is also considering retiring traditional MIPS, where it would no longer be available by the CY 2028 MIPS performance period/2030 MIPS payment year but would make any proposal to do so in a future rulemaking.

CMS believes, and proposes in this rule, that multispecialty groups reporting MVPs must form subgroups beginning with the 2025 performance period/2027 payment year to provide enhanced performance feedback to clinicians and to ensure more granular information is publicly available for patients.

STS is concerned that CMS is moving forward to implement MVPs without addressing underlying challenges carried over from MIPS. By not addressing these concerns, MVPs will not provide a more meaningful and less burdensome participation pathway for specialists or offer a practical glide path to APMs. Instead, CMS is adding yet another program requiring attention and resources that will further distract from shifting to value-based care.

The addition of a new pathway will add, not remove, complexity to the program for clinicians and registries. Given the limited time, staff, and financial resources available for clinicians to adapt processes that meet program requirements, each new program distracts from overarching efforts to transition to value-based care and ultimately alternative payment models. These multiple pathways also make it difficult for registries to focus efforts, leading to increased cost and complexity. For example, STS registries do not have the resources to support the new MVP program while also preparing and supporting members for advanced alternative payment models. STS urges CMS to refocus programmatic attention to reducing reporting burden and establishing a practical glidepath to alternative payment models.

STS urges CMS to consider addressing the following key issues MVPs have carried over from MIPS:

Reporting Issues

MIPS and QCDR reporting requirements have become increasingly burdensome. In addition to quality measures, registries are also required to collect, validate, and report data related to improvement activities and measures related to promoting interoperability. These new requirements are beyond the scope of registries and create additional cost and burden. QCDRs must now perform data audits for the data submitted under each performance category, adding additional complexity, cost, and burden.

Clinically Relevant Measures
Many MIPS measures lack the clinical relevance to cardiothoracic surgery that patients and clinicians value. Patients and clinicians alike value improvement in measures directly related to morbidity, mortality, and overall quality of life after surgery. Measures that provide meaningful insight into these factors are the focus of STS registries, cardiothoracic surgeons, and patients.

Alignment with APMs
MIPS and MVPs do not adequately align with APMs to create a practical glidepath to incentivize and ease surgeon transition to APMs. For example, STS recently worked with the Center for Medicare and Medicaid Innovation (CMMI) to incorporate STS registry measures into the BPCI-A APM Coronary Artery Bypass Grafting (CABG) and Cardiac Valve episodes. However, participants in BPCI-A who do not participate in the model at a sufficient level to qualify for the APM incentive payment and an exemption from MIPS, cannot get credit under MIPS for the quality measures they are already reporting under BPCI-A. Lack of measure alignment and the resulting duplicative reporting requirements are barriers to APM participation.

Siloed Performance Categories
Siloed performance categories within MIPS should not be extended into MVPs. STS recommends that MVPs recognize multi-category measures that simultaneously address two or three MIPS performance categories, such as quality measures reported to registries, that may also earn a clinician credit for Improvement Activities or Promoting Interoperability categories.

Incentives
MVPs do not create the right incentives for meaningful participation and are too burdensome/expensive for QCDRs to implement. For surgeons who participate in MIPS as part of hospital systems that report on general measures on surgeons' behalf, it is not clear how MVPs shift incentives to encourage surgeons to modify reporting habits and report more focused measures. While the MVP offers an opportunity to reduce reporting by one or two fewer quality measures/improvement activities, this is likely not adequate to persuade subgroups of cardiac surgeons to invest additional time and resources into the reporting of self-selected measures/activities separate from their larger groups or hospitals. Although STS appreciates that CMS considers subgroup reporting to be a solution, we are concerned that subgroup reporting will instead add more analytic complexity and cost to registries.

STS submits the following feedback related to specific proposals in the CY 2022 proposed rule:

Reducing Barriers to APMs
CMS included an MVP guiding principle stating that, "MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement." CMS discussed that APM participants may have more legal flexibility and APM models often use Innovation Center waiver authority.

STS commends the inclusion of this guiding principle and again emphasizes the importance of alignment between MIPS, MVPs, and APMs to encourage APM participation. For example, ensuring that BPCI-A measures are included in MVPs, and can be reported once for both programs, to reduce the adjustment required to shift from an MVP to BPCI-A. Including registry measures further streamlines clinician efforts

by reducing the resources necessary to participate in multiple programs. Many cardiothoracic surgeons already participate in STS registry programs—and we support any opportunity to align and consolidate the reporting and requirements across MIPS, MVPs, and APMs, which would greatly ease the burden of transitioning to APMs. STS encourages CMS to identify and begin addressing any legal or policy barriers to alignment between the MIPS, MVP, and APM programs as these remain a key barrier.

MVP Timeline
CMS proposes delaying implementation and availability of the proposed MVPs until the 2023 performance period/2025 MIPS payment year. For the first year, MVP reporting would be voluntary. CMS notes that in future rulemaking it may consider sunsetting traditional MIPS after CY 2027 and requiring mandatory MVP reporting starting CY 2028. Any proposal to sunset traditional MIPS would be officially made in future rulemaking.

Given the time and resources necessary to prepare for another complex program such as MVP, it is too premature to make a determination on the timeline to sunset traditional MIPS or mandate MVPs.

Requirements for QCDR Measures Considered for an MVP
QCDR measures that were approved in the previous year may be considered for inclusion within an MVP. QCDR measures should be fully tested at the clinician level prior to the QCDR measure being included in an MVP. CMS requires receipt of QCDR measure testing data by the end of the self-nomination period.

STS supports the use of QCDR measures in MVPs and encourages CMS to mitigate barriers to their timely use. Due to the vast QCDR access to real world specialty-specific clinical data, QCDRs are uniquely positioned to develop meaningful measures that demonstrate quality to clinicians and patients. These measures not only give insight into quality performance but are also relevant tools to facilitate and measure quality improvement relevant to the clinician specialty. For example, the STS measure for using a procedure specific risk calculator promotes patient engagement and share decision making.

A significant barrier to the timely use of QCDR measures remains the CMS requirement for QCDR measures to be fully tested at the clinician level prior to use in an MVP. Fully testing a measure at the clinician level is complex, expensive, and time-consuming. It can take several months to execute a testing contract with a testing vendor. Due to the large number of measures required to undergo testing, the limited number of testing vendors may be unable to support the increased demand, creating additional delays. The burden of this requirement is so great that it will likely delay inclusion of QCDR measures in MVPs or even reduce the ability for QCDRs to provide any measures for MVPs. Given the value of these meaningful measures, this will have a negative impact on the perceived relevance and engagement in MVPs. Furthermore, once a QCDR measure is fully tested, a significant additional delay will occur if the MVP deadline to submit new measures does not align with the QCDR measure development cycle.

STS reiterates previously submitted concerns that increasingly burdensome requirements placed on QCDRs will jeopardize their participation in QPP. STS has participated in quality reporting since its inception by utilizing existing real world clinical registry data for quality measurement, which is crucial to reduce provider burden and to provide quality measures that are meaningful to patients and providers. The STS National Database has decades of experience collecting and tracking quality data and finds the increasingly burdensome and unreasonable QCDR requirements place an almost prohibitive difficulty on

maintaining QCDR status. These QCDR policies have eliminated important measures for cardiothoracic surgeons and placed overly burdensome audit and data submission requirements on QCDRs. As discussed later in this comment letter, STS urges CMS to reduce QCDR burden to maintain their ability to facilitate clinician participation and quality improvement in the QPP.

QCDR Support of MVP and Subgroup Reporting
CMS will require QCDRs to support MVP and MVP subgroup reporting.

As discussed in more detail later in these comments, STS is concerned that QCDRs may lack the existing capacity to support these programs and will be required to engage in major financial and systematic changes to meet these requirements.

d. MIPS Performance Category Measures and Activities

Quality Category

CMS proposes to use 2022 performance to set 2022 quality benchmarks, rather than 2020 historic performance due to impact of COVID. CMS is also considering and seeking feedback as an alternative to performance period benchmarks, utilizing the historic benchmarks from the 2021 MIPS performance period (which are based on submissions for CY 2019 MIPS performance period/2021 MIPS payment year) for the CY 2022 performance period/2024 MIPS payment year. CMS believes this option would allow clinicians to continue to receive advance notice for quality performance category measures so that MIPS eligible clinicians can set a clear performance goal for these measures for the CY 2022 performance period/2024 MIPS payment year.

STS supports the CMS proposal to use 2022 performance data, instead of the 2020 performance, to set the 2022 quality benchmarks due to the impact of the COVID-19 pandemic, as well as the CMS proposal to provide 2019 historic benchmarks to give clinicians a target. This alternative would balance the need to provide benchmark data ahead of time while also relying on the most recent data when possible. STS appreciates the CMS effort to adapt given COVID PHE disruptions.

Cost Category

CMS has identified that there is a need for additional flexibility in calculating the scores for cost measures to account for the impact of changing conditions (e.g., the COVID-19 PHE) that are beyond the control of MIPS eligible clinicians and groups. As such, CMS proposes that, beginning with the 2024 MIPS payment year, if data used to calculate a score for a cost measure are impacted by significant changes during the performance period, such that calculating the cost measure score would lead to misleading or inaccurate results, then the affected cost measure is excluded from the MIPS eligible clinician's or group's cost performance category score.

STS strongly supports excluding cost measures that are significantly impacted by changing conditions that are beyond the control of the MIPS eligible clinicians and groups. As the COVID-19 public health emergency has demonstrated, it is critical that the MIPS program allows for adjustment during unforeseen circumstances that do not accurately reflect clinician performance.

In response to stakeholder interest in expanding the limited inventory of cost measures available to specialties, CMS proposes to establish a process, beginning in CY 2022, for the development of cost measures by stakeholders, outside of the current development process, that would ensure that the cost performance category has consistency across measures, aligns with CMS priorities, and is consistent with the Meaningful Measures Framework. Episode-based measures developed by stakeholders that meet the standards and criteria proposed for selecting measures would contribute to the target of an estimated 50% of expenditures under parts A and B, as described in section 1848(r)(2)(D)(i)(I) of the Act.

STS appreciates the proposed CMS effort to consider and implement stakeholder-developed cost measures outside of the current process. Cost measures should relate to quality and be actionable and appropriate for clinician-level accountability. STS urges CMS to consider innovative approaches to cost measurement, including using resource utilization measures over which clinicians have control, such as ICU time, transfusions, vent times or length of stay as surrogates for cost. Specialty-specific cost performance data is also critical in developing new cost measures and understanding which current cost measures require improvements.

Clinician-led clinical data registries, when combined with comprehensive Medicare claims data, provide a unique opportunity to facilitate research into the most effective and cost-efficient patient care—invaluable insight in meaningful and actionable cost measure development. Unfortunately, CMS has not provided clinician-led clinical data registries, including The STS National Database, sufficient access to Medicare claims data. Section 105(b) of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") directs the Secretary of Health and Human Services to provide Medicare claims data to QCDRs "for purposes of linking such data with clinical outcomes data and performing risk-adjusted, scientifically valid analyses and research to support quality improvement or patient safety." These data, when combined with registry clinical data, provide insight into longitudinal patient outcomes and cost that can aid in the development of meaningful cost measures. ***Only then can cost be used as a measure of health care value.***

Promoting Interoperability

CMS proposes to require 2 of the measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the performance period in CY 2022 (unless exclusion applies): Immunization Registry Reporting; and Electronic Case Reporting. Bonus point for reporting on any one of the following: Public Health Registry Reporting, Clinical Data Registry Reporting, or Syndromic Surveillance Reporting measure.

STS supports CMS offering a bonus point for reporting on Clinical Data Registry reporting.

d. MIPS Final Score Methodology

Final Score Performance Category Weights

For CY 2022 MIPS performance period/CY 2024 MIPS payment year and each subsequent MIPS payment year, CMS proposes decreasing the Quality performance category and increasing the Cost performance category weight:

Performance Category	***2022 Performance Period/2024 and Future MIPS Payment Years***
Quality	*30%*
Cost	*30%*
Improvement Activities	*15%*
Promoting Interoperability	*25%*

STS understands that CMS is following statutory requirements to weigh Quality and Cost each at 30%. However, we strongly recommend against implementing this requirement during the ongoing COVID-19 PHE. Clinicians continue to focus efforts on treating patients with COVID-19 and again are facing pandemic-related delayed care and unusual care volumes. Pandemic-related cost increases for staffing and equipment may not reflect the usual and customary costs of providing care. By increasing the cost performance category weight, CMS would be relying on cost data that more accurately reflects the realities of pandemic response financing and care volume than actual clinician performance. Furthermore, clinicians do not have the time or resources during the COVID-19 PHE to devote to adjusting practice operations and data tracking to attempt to account for shifting CMS performance category weight.

Additionally, by decreasing the weight of the quality performance category, CMS is undermining the importance of quality and instead further relying on components over which providers have little or no control even without a public health emergency. Cost measures remain siloed data points that are not directly tied to quality measures. Clinicians have far more direct control over quality measures than they do over the current set of cost measures. Until CMS works with stakeholders to develop cost measures that are tied to quality measures and give clinicians a real opportunity for impact, the quality performance category should continue to be weighted higher than the cost performance category.

STS strongly urges against increasing the cost performance category weight to 30% and decreasing the quality performance category weight to 30% due to the ongoing COVID-19 PHE and continuing cost measurement challenges. We urge CMS to consider flexibilities granted as a result of the PHE to temporarily waive this statutory requirement.

f. MIPS Payment Adjustments

Establishing the Performance Threshold

For CY 2022, CMS proposes increasing the MIPS performance threshold to 75 points, up from 60 points. The exceptional performance threshold would be increased to 89 points, up from 85 points. Per MACRA, 2022 will be the last performance year that exceptional performance will be rewarded.

Although STS appreciates that CMS has chosen the lowest value possible (75 points) in compliance with the statute, we strongly urge CMS to consider instead implementing PHE flexibilities regarding these proposed increase to the MIPS performance threshold. By making positive adjustments more difficult to obtain, especially as the COVID-19 pandemic continues, clinicians may become frustrated and lose motivation to engage.

We recognize that the CMS selection of the mean methodology and final score data from the 2019 MIPS payment year gives two options for setting the exceptional performance threshold: 81.26 points or

88.94 points. Instead of rounding up the highest option to 89 points, we urge CMS to use PHE flexibilities to maintain the exceptional performance threshold at 85 points. Maintaining the current threshold would give more clinicians a final opportunity to qualify for this funding and take into account the unusual operational and clinical circumstances present during the COVID-19 pandemic.

Finally, STS respectfully requests that CMS not finalize other disadvantageous scoring policies that would make it more difficult to meet the threshold (e.g., 0 points for measures that lack a benchmark).

h. Third Party Intermediaries

CMS proposes to create a new requirement to state that, beginning with the 2023 MIPS performance period/2025 MIPS payment year, QCDRs and qualified registries must support MVPs that are applicable to the MVP participants on whose behalf they submit MIPS data. QCDRs and qualified registries may also support the APP. CMS also proposes to require QCDRs, qualified registries, health IT vendors, and CAHPS for MIPS survey vendors to support subgroup reporting, beginning with the 2023 MIPS performance period/2025 MIPS payment year.

This new requirement further complicates QCDR requirements and will likely prompt discussion on what level of programmatic support they can reasonably offer to CMS and the QPP program with the limited resources, time, and staff.

CMS developed MVP and subgroup reporting requirements without QCDR stakeholder consideration for what is technically and financially feasible. As such, QCDRs will likely be required to shift other priorities, including supporting alternative payment model development and other quality improvement initiatives, to invest in systematic changes that would allow this level of support to MVPs and subgroup reporting. For example, the STS registries with QCDR status do not have the capacity to support subgroup reporting. To enable this capacity, STS would need to redirect resources and potentially delay attention to other programs that more directly lead to improved patient care.

STS recommends that CMS work with QCDR stakeholders to ensure that such requirements are workable and remain voluntary in the interim.

STS also seeks clarification on whether QCDRs and QRs are *required* or *permitted* to support the APM Performance Pathway (APP). In the preamble to the Proposed Rule, CMS states that it is "proposing that beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, QCDRs and qualified registries *must* support the APP."[4] This language suggests that CMS is proposing a requirement. However, the proposed regulatory text provides that "QCDRs and qualified registries *may* also support the APP," indicating that such support is permitted, not required.[5]

STS opposes the establishment of a requirement to support the APP as QCDRs and QRs currently are not in a position to provide such support. In order to comply with such a requirement, QCDRs and QRs would need to make operational changes, which would greatly increase vendor cost and strain staffing resources.

[4] CY 2022 MPFS, 86 Fed. Reg. at 39,483.
[5] *Id*. at 39,587 (emphasis added).

New Requirements for Both Qualified Clinical Data Registries (QCDRs) and Qualified Registries Data Validation Audit and Targeted Audit Requirements

In the CY 2021 PFS final rule (85 FR 84930 through 84937; 85 FR 84944 through 84947), CMS finalized the data validation audit requirements as condition for QCDR approval. However, CMS did not codify the requirements for QCDR and qualified registries to submit a data validation plan during self-nomination along with the results of the executed data validation plan by May 31 of the year following the performance period, which are requirements that were discussed in the CY 2017 QPP final rule (81 FR 77366 through 77367; 81 FR 77383 through 77384). In order to provide clarification and to better align with the previously finalized policy, CMS proposes to codify these requirements.

Furthermore, QCDRs and qualified registries are required to submit their data validation plan explaining their process of data validation submission annually during self-nomination, and it must be approved by CMS for before use. To provide further clarity and to better align with the existing policy (81 FR 77366 through 77367; 81 FR 77383 through 77384), CMS also proposes to codify a new requirement to state that, beginning with the CY 2023 MIPS performance period/2025 MIPS payment year, the QCDR or qualified registry must submit a data validation plan annually, at the time of self-nomination, for CMS' approval, and may not change the plan once approved, without the prior approval of the agency.

STS reiterates previous concerns regarding these CMS data validation audit requirements. As a QCDR, STS and the STS National Database have long been active stakeholders in CMS QCDR policies. The increasingly burdensome audit and data validation requirements continue to place unreasonable financial and operational expectations on QCDRs, risking their ability to continue supporting CMS quality programs. QCDRs have rigorous internal quality data standards which should be recognized and accepted by CMS. The additional requirements are unnecessarily duplicate, burdensome, and costly. The STS National Database hires an external auditing firm to conduct audits for 10% of participating sites at significant cost to the organization. Provider level audits have added to this financial burden, are time consuming, and do not enhance overall data quality or validity. Given the lessons learned from the impact of the COVID-19 pandemic on hospitals and registries, it would be unwise to adopt rigid requirements. Some flexibility should be considered.

New Requirements Specific to QCDRs

CMS proposes to codify another QCDR measure rejection criterion to state that if a QCDR measure owner is not approved during a given self-nomination period, any associated QCDR measures with that QCDR would also not be approved. CMS has received inquiries from stakeholders on what can be done in circumstances when an active QCDR wishes to use an inactive QCDR's measures.

STS supports allowing an active QCDR to use measures from an inactive QCDR provided they obtain permission.

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STS appreciates the opportunity to share this feedback with CMS. Should you have any questions about our comments or concerns, please contact STS Vice President of Government Relations Courtney Yohe at 202-787-1222 or cyohe@sts.org.

Sincerely,

Sean C. Grondin, MD
President

Appendix A

Appendix A – STS Recommended Revisions to CY 2022 Anticipated Specialty List			
CPT Code	**Anticipated Specialty**	**STS Recommended Specialty**	**STS Recommended Action**
19272	THORACIC SURGERY		Add to list
32501	THORACIC SURGERY		Add to list
32540	THORACIC SURGERY		Add to list
33417	CARDIAC SURGERY		Add to list
33440	CARDIAC SURGERY		Add to list
33910	CARDIAC SURGERY		Add to list
33983	CARDIAC SURGERY		Add to list
31760	THORACIC SURGERY		Reactivate
31775	THORACIC SURGERY		Reactivate
32215	THORACIC SURGERY		Reactivate
32491	THORACIC SURGERY		Reactivate
32654	THORACIC SURGERY		Reactivate
32672	THORACIC SURGERY		Reactivate
32800	THORACIC SURGERY		Reactivate
32900	THORACIC SURGERY		Reactivate
33140	CARDIAC SURGERY		Reactivate
33238	CARDIAC SURGERY		Reactivate
33254	CARDIAC SURGERY		Reactivate
33320	THORACIC SURGERY	CARDIAC SURGERY	Reactivate – change specialty
33363	CARDIAC SURGERY		Reactivate
33475	CARDIAC SURGERY		Reactivate
33548	CARDIAC SURGERY		Reactivate
33610	THORACIC SURGERY	CARDIAC SURGERY	Reactivate – change specialty
33615	THORACIC SURGERY	CARDIAC SURGERY	Reactivate – change specialty
33617	THORACIC SURGERY	CARDIAC SURGERY	Reactivate – change specialty
33684	THORACIC SURGERY	CARDIAC SURGERY	Reactivate – change specialty
33690	THORACIC SURGERY	CARDIAC SURGERY	Reactivate – change specialty
33726	THORACIC SURGERY	CARDIAC SURGERY	Reactivate – change specialty
33735	THORACIC SURGERY	CARDIAC SURGERY	Reactivate – change specialty
33767	THORACIC SURGERY	CARDIAC SURGERY	Reactivate – change specialty
33916	CARDIAC SURGERY		Reactivate
33985	CARDIAC SURGERY		Reactivate
33991	CARDIAC SURGERY		Reactivate
35271	CARDIAC SURGERY		Reactivate
64410	THORACIC SURGERY		Reactivate
33203	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33251	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33414	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33468	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33470	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33471	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33474	CARDIAC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33476	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33478	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment

Appendix A

Appendix A – STS Recommended Revisions to CY 2022 Anticipated Specialty List			
CPT Code	**Anticipated Specialty**	**STS Recommended Specialty**	**STS Recommended Action**
33502	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33503	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33504	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33505	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33506	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33507	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33600	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33602	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33606	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33608	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33611	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33612	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33619	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33620	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33621	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33622	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33645	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33647	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33660	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33665	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33670	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33675	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33676	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33677	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33688	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33692	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33694	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33697	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33702	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33710	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33720	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33722	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33724	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33730	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33732	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33736	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33737	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33750	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33755	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33762	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33764	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33766	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33768	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33770	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment

Appendix A

Appendix A – STS Recommended Revisions to CY 2022 Anticipated Specialty List			
CPT Code	**Anticipated Specialty**	**STS Recommended Specialty**	**STS Recommended Action**
33771	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33774	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33775	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33776	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33777	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33778	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33779	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33780	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33781	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33782	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33783	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33786	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33788	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33800	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33802	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33803	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33813	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33814	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33820	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33822	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33824	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33840	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33845	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33851	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33852	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33853	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33917	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33920	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33922	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33924	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33925	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33926	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
33927	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
35182	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
36835	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
38382	THORACIC SURGERY	CARDIAC SURGERY	Change Specialty Assignment
21603	PLASTIC AND RECONSTRUCTIVE SURGERY	THORACIC SURGERY	Change Specialty Assignment
31781	THORACIC SURGERY	OTOLARYNGOLOGY	Change Specialty Assignment
35180	THORACIC SURGERY	VASCULAR SURGERY	Change Specialty Assignment
43313	THORACIC SURGERY	GENERAL SURGERY	Change Specialty Assignment
43314	THORACIC SURGERY	GENERAL SURGERY	Change Specialty Assignment
96440	THORACIC SURGERY	HEMATOLOGY ONCOLOGY	Change Specialty Assignment

C-TAC
COALITION TO TRANSFORM ADVANCED CARE

1299 Pennsylvania Avenue NW
Suite 1175
Washington, DC 20004

September 13, 2021

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements

On behalf of the Coalition to Transform Advanced Care (C-TAC), we appreciate the opportunity to provide comments on this proposed rule in regard to its effects on those living with serious illness.

C-TAC is a national non-partisan, not-for-profit coalition dedicated to ensuring that all those living with serious illness, especially the sickest and most vulnerable, receive comprehensive, high- quality, person- and family-centered care that is consistent with their goals and values and honors their dignity. C-TAC is made up of over 170 national and regional organizations including patient and consumer advocacy groups, practitioners, health plans, faith-based and community organizations, and others who share a common vision of improving care for serious illness in the U.S.

Telehealth Services

- Category 3 list- We support extending the Category 3 list of telehealth services through 2023 and appreciate CMS's using that time to learn more about these remote interventions.

- Mental health delivered via telehealth- We strongly suggest that audio-only be offered as an option to all beneficiaries rather than making it only available when the beneficiary is not capable of using, or does not consent to, the use of two-way, audio/video technology. It may actually be easier for beneficiaries to engage in mental telehealth via audio-only as this puts the focus on the conversation and not on the person's appearance or visual communication skills. All health interventions should be delivered in accord with the person's preferences, and we suggest that audio-only be offered as a standard telehealth option. We do not feel that additional documentation should be required or that beneficiaries should need to give specific consent to audio-only, just that it be offered, and their preference noted in the clinical chart.

- Audio-only for other services- We also strongly recommend that CMS extend the ability for audio-only for additional telehealth services, most especially advance care planning. CMS Administrator Ms. Brooks-LaSure recently emphasized that person-centered care is a priority for the agency[i] and to best ensure such care, processes like advance care planning should be prioritized. This process via audio-only telehealth was very important during the pandemic and not just for end-of-life planning, but to promote goals of care conversation throughout a person's illness. Using audio-only telehealth is another way of making it accessible to all beneficiaries, regardless of their broadband or video capabilities. And allowing beneficiaries to honor their preference for audio-only is another way to engage them directly in their care.

- Home as an originating site- We want to again advocate to make some of the pandemic waivers permanent including home as the originating site. This is particularly important for those living with serious illness, and their families, who may have functional and transportation challenges with seeing a provider in person, but who would benefit from telehealth encounters instead.

- Allowing practice across state lines- We continue to support removing licensure restrictions to allow clinicians to practice telehealth across state lines. This has also been a helpful change during the pandemic and should be extended permanently.

- Payment- Finally, we ask that CMS pay telehealth interactions such as mental health and advance care planning at the same rate as in person since they are indeed the same service, just rendered remotely.

Physician Assistant (PA) Services

We support allowing PAs to bill Medicare directly for their services and reassign payment for their services. This will be of great use to interdisciplinary teams delivering care to those with serious illness and using PAs to help do so.

Rural Health Center (RHCs) or Federally Qualified Health Centers (FQHCs) Payments

- Attending Physician Services Furnished by RHCs or FQHCs to Hospice Patients-We strongly support making FQHCs and RHCs eligible to receive payment for hospice attending physician services when provided by a FQHC/RHC physician, nurse practitioner, or physician assistant who is employed or working under contract for an FQHC or RHC, but is not employed by a hospice program, starting January 1, 2022. FQHCs and RHCs are an important part of health care and allowing them to provide hospice the same way other clinics and providers do will extend access to this important service for those living with serious illness in underserved areas. We encourage CMS to confirm that, after the patient's hospice election, the patient can name an attending provider and change that attending provider at *any time* during hospice care.

- Concurrent Billing for Chronic Care Management Services (CCM) and Transitional Care Management (TCM) Services for RHCs and FQHCs- We also support the proposal to allow RHCs and FQHCs to bill for TCM and other care management services furnished for the same beneficiary during the same service period, provided all requirements for billing each code are met. Again, these are important aspects of care for serious illness and providers delivering care in these settings should have the same abilities to concurrently bill as in other clinical settings.

Pulmonary Rehabilitation

We support expanding coverage of outpatient pulmonary rehabilitation services, paid under Medicare Part B, to beneficiaries who were hospitalized with COVID-19 and experience persistent symptoms, including respiratory dysfunction, for at least four weeks after hospitalization. We are concerned about the new growth in the population of those with serious illness post-COVID-19 and agree that they should have access to needed services to improve or maintain function, if possible.

Other Payment Changes

We do not support the following proposed payment changes and do not have suggestions on how to achieve budget neutrality by forgoing them, yet feel these are the wrong places to make cuts:

- Proposed Payments for Evaluation & Management (E/M) Services in 2022- We do not support the proposed payment decreases to the home (CPT 99341-99350) and domiciliary (CPT 99347-99350) E/M services in CY 2022. Our members tell us this threatens the sustainability of many innovative programs, such as house call programs, and we instead recommend CMS continue the 3.75 payment increase to the conversion factor. We hear that house call clinicians are already at a disadvantage in payment compared to office-based practices and the current fee schedule payment rates for home and domiciliary services do not adequately reimburse for the comprehensive-person-centered care provided under fee-for-service. This is unfortunate since many with serious illness are unable to easily go to in-person clinical visits and would be better served by care provided in the home. In fact, that is one of the key learnings of the pandemic and we need instead to find ways to make home-based care for this population both more accessible *and* financially sustainable.

- Physical therapy (PT)/Occupational therapy (OT) payment reduction- We do not support the proposal to impose a 3.5 percent cut to physical and occupational therapists in 2022. Taken together with the compounding impact of successive cuts to that specialty, physical and occupational therapists will eventually face a steep 9 percent payment cut by 2024. PT and OT services are important to those with serious illness to maintain or slow the decline in function and, therefore, contribute to quality of life for them and their loved ones.

Proposed MIPS Value Pathways (MVPs)
We support the proposal to make 7 MVPs available beginning with the 2023 performance year and would note that all 7 relate to aspects of serious illness. Our only recommendation is that additional ones be considered in the future such as end-stage renal disease (ESRD), chronic obstructive pulmonary disease (COPD), and possibly even geriatrics/frailty. We and our members would be happy to work with the agency on the details of such future MVPs.

Traditional MIPS Program Proposals - MIPS Eligible Clinician Definition
We appreciate the recognition of the importance of clinical social workers and their addition to the list of MIPS eligible clinicians. They are an important part of the interdisciplinary teams providing care to those with serious illness.

Improvement Activities Performance Category
We appreciate and are in support of the proposal to add new improvement activities about health equity and standardizing language related to equity across the improvement activities inventory. Health equity has been an important priority for C-TAC from the beginning and we feel these changes will help to address inequity in the health care system. We are also grateful that advance care planning is one of the improvement activities and would be happy to work with the agency to promote this an in important option for MIPS providers.

Thank you for the opportunity to comment on this proposed rule. If you have any questions, please contact Marian Grant, Senior Regulatory Advisor, C-TAC, at mgrant@thectac.org.

Sincerely,

Marian Grant

Marian Grant, DNP, CRNP, ACHPN, FPCN
Senior Regulatory Advisor
Coalition to Transform Advanced Care (C-TAC)
1299 Pennsylvania Ave, Suite 1175
Washington, DC, 20008

[i] https://www.healthaffairs.org/do/10.1377/he20210803.199350/full/